BACK SIDE / PLEASE, INCLUDE YOUR DESIGN ON THIS KEYLINE

10 mm 20 mm 690 mm 720 mm

Drospirenone

Slinda

4mg Film-Coated Tablet
Hormonal Contraceptive

Rx

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Basahin nang mabuti ang lahat ng nakasulat sa babasahing ito bago inumin ang gamot dahil mayroong mahahalagang impormasyon para sa iyo.

- Keep this leaflet. You may need to read it again.
  Itago ang babasahing ito sakaling kailanganin mong basahing muli.
- If you have any further questions, ask your doctor or pharmacist.
  Kung mayroon kang karagdagan na katanungan, kausapin mo ang iyong doktor o pharmacist.
- This medication has been prescribed for you only. Do not pass it on to others. It may harm them.
  Inireseta ang gamot na ito para sa iyo lamang. Huwag mo itong ipapasa sa iba dahil maaari itong makasama sa kanila.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.
  Kung makaramdam ka ng ibang mga epekto, kausapin mo ang iyong doktor o pharmacist. Maaaring magkaroon ng ibang mga epekto na hindi naisama sa babasahing ito, pakitingnan ang seksyon 4.

WHAT IS IN THIS LEAFLET ***ANO ANG NILALAMAN NG BABASAHING ITO?***

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   Ano ang Drospirenone at ano ang gamit nito
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1. What Drospirenone (Slinda) is and what it is used for ***Ano ang Drospirenone at ano ang gamit nito***

Drospirenone (Slinda) is a contraceptive pill and is used to prevent pregnancy. Each blister of Drospirenone (Slinda) contains 24 white tablets, also called active tablets, and 4 green tablets, also called placebo tablets, that do not contain active substance. The two differently coloured tablets are arranged in order.
Ang Drospirenone (Slinda) ay isang kontraseptibong pildoras at ginagamit upang maiwasan ang pagbubuntis. Ang isang banig o blister ng Drospirenone (Slinda) ay naglalaman ng 24 na kulay puting pildoras na tinatawag ding aktibong tabletas. Kasama rin ang apat na kulay berdeng tabletas na tinatawag namang plasibong pildoras na hindi naglalaman ng aktibong sangkap. Nakahanay ng maayos ang dalawang magkaibang uri ng may kulay na pildoras.

Each of the 24 white active tablets contains a small amount of one type of female sex hormone, the progestogen drospirenone. For this reason Drospirenone (Slinda) is called a progestogen-only-pill (POP). Contrary to the combined pills, POPs don't contain any oestrogen hormone next to the progestogen. For this reason, Drospirenone (Slinda) can be used by women who do not tolerate oestrogens.
Ang bawat isa sa 24 na tableta ay naglalaman ng kaunting sukat ng isang uri ng pambabaeng hormone, ang progestogen drospirenone na nasa bawat isang puting aktibong tableta. Dahil dito, tinatawag na progestogen-only-pill (POP) ang Drospirenone (Slinda). Salungat sa pinagsanib na pildoras, hindi kasi naglalaman ng oestrogen hormone kasunod ng progestogen ang POP's. Dahil dito, maaaring gamitin ang Drospirenone (Slinda) ng mga babaeng hindi umiinom ng mga oestrogen.

Drospirenone (Slinda) provides high contraceptive efficacy. The contraceptive effect of Drospirenone (Slinda) is based on the inhibition of ovulation, changes in the cervical mucus and effects on the endometrium, which becomes thinner.
Ang Drospirenone (Slinda) ay nagtataglay ng mataas na bisa bilang kontraseptib. Ang kontraseptibong epekto ng Drospirenone (Slinda) ay batay sa pagpigil ng ovulation, pagbabago sa cervical mucus at epekto nito sa endometrium kung saan ito ay numinipis.

A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of Drospirenone (Slinda). You also may not have any bleeding at all.
Maaaring magkaroon ng hindi regular na pagdurugo ang ari ng babae habang umiinom ng Drospirenone. (Slinda). Maaari rin naman na hindi makaranas ng pagdurugo.

2. What you need to know before you take Drospirenone (Slinda) ***Ano ang dapat mong malaman bago ka uminom ng Drospirenone (Slinda)?***
Do not take Drospirenone (Slinda): ***Huwag iinom ng Drospirenone (Slinda):***
- if you are allergic to drospirenone or any of the other ingredients of this medicine (listed in section 6).
  Kung ikaw ay allergic sa Drospirenone o anumang iba pang sangkap ng gamot (Nakalista sa Seksyon 6).
- if you have a blood clot in a blood vessel e.g. of the legs (deep venous thrombosis) or of the lungs (pulmonary embolism).
  Kung mayroon kang namuong dugo halimbawa sa binti (deep venous thrombosis) o sa baga (pulmonary embolism).
- if you have or have had a liver disease and your liver function is still not normal.
  Kung mayroon o nagkaroon na ng sakit sa atay at hindi na ito gumagana ng normal
- if your kidneys are not working well (renal failure).
  Kung hindi gumagana nang maayos ang bato (pagpalya ng bato o renal failure)
- If you have reduced adrenal gland function (adrenal insufficiency).
  Kung nabawasan ang kakayahan ng iyong adrenal gland (adrenal insufficiency).
- if you have or are suspected to have a cancer that is sensitive to sex-steroids, such as certain types of breast cancer.
  Kung mayroon na o pinaghihinalaang pa lang na may kanser na sensitibo sa sex-steroids, tulad ng ibang uri ng kanser sa suso.
- if you have any unexplained vaginal bleeding.
  Kung may hindi maipaliwanag na pagdurugo sa pwerta o ari ng babae

If any of these conditions appear when using Drospirenone (Slinda), stop taking this medicine immediately and contact your doctor.
Kung nakitaan ng alinman sa mga kondisyon na ito habang gumagamit ng Drospirenone (Slinda), ihinto kaagad ang pag-inom at kontakin ang iyong doktor.

Warnings and precautions ***Mga Babala at Pag-iingat***
Drospirenone (Slinda), like other hormonal contraceptives, does not protect against HIV (Human Immunodeficiency Virus) infection, AIDS (Autoimmune Deficiency Syndrome) or any other sexually transmitted disease.
Ang Drospirenone (Slinda) katulad ng ibang kontraseptibong hormonal ay hindi kayang mapigilan ang impeksyon dulot ng HIV (Human Immunodeficiency Virus), AIDS (Autoimmune Deficiency Syndrome) at iba pang nakakahawang sekswal na mga sakit.

Talk to your doctor before starting to use Drospirenone (Slinda) if any of the following conditions apply to you:
Kumonsulta sa iyong dockor bago simulan ang paggamit ng Drospirenone (Slinda) kung ang mga sumusunod ay maaaring angkop sa iyo:
- you have ever had a thrombosis (formation of a blood clot in a blood vessel).
  nagkaroon ka ng thrombosis (pamumuo ng dugo sa daluyan nito)
- you have liver cancer, if you have jaundice (yellowing of the skin) or liver disease and your liver is not working normally.
  mayroon kang kanser sa atay, naninilaw ang iyong balat (jaundice) o may sakit ka sa atay at hindi ito gumagana ng normal
- you have ever had breast cancer. *nagkaroon ka ng kanser sa suso*
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly on the face); if this is the case, you will need to avoid exposure to the sun or ultraviolet radiation during treatment with Drospirenone (Slinda).
  nagkaroon ka o mayroon kang patse-patseng kulay kape na madilaw sa iyong balat lalo na sa mukha; kung may ganito ka, kailangan mong iwasan ang pagbibilad sa araw o ultra violet radiation habang gumagamit ka ng Drospirenone (Slinda)
- diabetes. *diabetes*
- you have high blood pressure. *alta presyon o mataas na presyon ng dugo*
- your kidneys are not working well, as your doctor will do a blood test to check potassium levels during the first cycle.
  hindi gumagana nang maayos ang iyong bato, kailangang gumawa ang iyong doktor ng pagsusuri sa iyong dugo para sa antas ng potassium sa una pa lamang siklo ng paggamit.

If you suffer a worsening or first appearance of any of these conditions, you should contact your doctor. Your doctor should then decide whether you should stop taking Drospirenone (Slinda) and may advice you to use a non-hormonal method of birth control.
Kung matindi ang iyong naranasan o nagkaroon ng unang pagpapakita ng mga kondisyong nabanggit, kailangan mong kontakin ang iyong doktor. Siya ang magpapasya kung itutuloy o ihihinto mo na ang paggamit ng Drospirenone (Slinda). Mapapayuhan ka rin niya na gumamit ng non-hormonal na paraan ng pagpigil sa pagbubuntis

Breast cancer Kanser sa suso
Regularly check your breasts and contact your doctor as soon as possible if you feel any lump in your breasts.
Regular na eksaminin ang iyong suso at kontakin ang iyong doctor sa lalong madaling panahon kung nakakaramdam ka na parang may bukol ka sa iyong suso.

Breast cancer has been found slightly more often in women who take the combined Pill than in women of the same age who do not take the combined Pill. If women stop taking the combined pill, the risk gradually decreases, so that 10 years after stopping the risk is the same as for women who have never taken the combined Pill.
Napag-alaman na ang kanser sa suso ay mas bahagyang nakikita sa mga babaeng magkakapareho ang edad na gumagamit ng magkasanib na pildoras. Kung dahan-dahang ihihinto ng mga babae ang paggamit ng magkasanib na pildoras, ang panganib ay dahan -dahan ding mababawasan kaya sa sampung taon pagkatapos tumigil, ang panganib ay kapareho na lamang ng mga babaeng hindi uminom ng magkasanib na pildoras.

Breast cancer is rare under 40 years of age. Breast cancers found in women who take the combined Pill, seem less likely to spread than breast cancers found in women who do not take the combined Pill. It is not known whether the difference in breast cancer risk is caused by the combined Pill. It may be that the women were examined more often, so that the breast cancer is noticed earlier.
Bihira ang kanser sa suso sa edad na hindi baba sa apatnapung taon (40). Ang kanser sa suso na nakikita sa mga babaeng umiinom ng pinagsanib na pildoras ay mas hindi kumakalat kumpara sa kanser sa suso ng mga umiinom ng hindi pinagsanib na pildoras. Hindi alam kung ang pagkakaiba ng panganib sa kanser sa suso ay dulot ng pinagsanib na pildoras. Marahil mas malimit na eksaminin ang mga babae ng mas maaga kaya agad nakitaan sila ng kanser sa suso.

The risk of breast cancer in users of progestogen-only preparations like Drospirenone (Slinda) is believed to be similar to that in women who use the combined Pill, but the evidence is less conclusive.
Ang panganib ng kanser sa suso sa mga gumagamit ng progestogen lamang na pildoras (POP) tulad ng Drospirenone (Slinda) ay pinaniniwalaang pareho lamang sa mga babaeng gumagamit ng pinagsanib na pildoras ngunit ang ebidensya ay kulang pa para mas makatiyak.

Thrombosis (formation of a blood clot in a blood vessel) Thrombosis (Pamumuo ng dugo sa daluyan nito)
See your doctor immediately, if you notice possible signs of a thrombosis (see also 'Regular check-ups').
Kumonsulta kaagad sa iyong doktor kung nakakita ng mga posibleng senyales ng thrombosis (Tingnan din ang "Regular na check -ups "o pagkonsulta)

Thrombosis is the formation of a blood clot, which may block a blood vessel. A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". As a result, fatal situations may occur.
Ang thrombosis ay pamumuo ng dugo na maaaring bumara sa daluyan nito. Kung minsan, ang thrombosis ay maaaring makita sa malalalim na daluyan ng dugo sa binti (deep venous thrombosis). Kapag ang namuong dugo ay matanggal mula sa bahaging pinagmulan nito, maaaring makarating ito at bumara sa daluyan ng dugo na nasa baga at magdulot ng tinatawag na "pulmonary embolism". Maaaring magdulot ng malubhang sitwasyon.

There may be a slightly increased risk of thrombosis with progestogen-only preparation. The risk of thrombosis is higher if a member of your family (a sibling or a parent) has had thrombosis at an relatively early age, with increasing age, obesity, prolonged immobilization, major surgery or major trauma. There is no apparent risk of having a heart attack or stroke (a blood clot in the brain) with a progestogen-only preparation. The risk is rather related to increasing age, increase in blood pressure and smoking. The risk of stroke may be slightly increased in women with high blood pressure when taking progestogen-only preparation. *Maaaring magkaroon ng bahagyang pagtaas ng panganib sa thrombosis gamit ang progestogen lamang na pildoras. Mas mataas ang panganib kung ang miyembro ng pamilya (kapatid o magulang) ay nagkaroon ng thrombosis noong murang edad pa lamang, mas nagkakaedad, mataas ang timbang, matagal na hindi pagkilos, matinding operasyon o matinding trauma. Wala namang nakikitang panganib ng pagkakaroon ng atake sa puso o istrok (pamumuo ng dugo sa utak) gamit ang progestogen lamang na pildoras. Ang panganib ay mas iniuugnay sa mas nagkakaedad, mataas na presyon ng dugo at paninigarilyo. Ang panganib ay bahagya ring iniuugnay sa mga babaeng may mataas ang presyon ng dugo habang umiinom ng progestogen lamang na pildoras.*

Psychiatric disorders Sakit sa isipan
Some women using hormonal contraceptives including Drospirenone (Slinda) have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.
Mayroong mga ilang kababaihan na gumagamit ng kontraseptibong hormonal kasama na ang Drospirenone (Slinda) ang nag-ulat ng depresyon o labis na kalungkutan. Maaaring malubha ang depresyon na posibleng makapag-isip ng pagpapakamatay. Kontakin ang iyong doktor sa lalong madaling panahon kung makakaranas ka ng ganitong pagbabago sa sarili at ng mga sintomas ng depresyon para sa mga payong medikal.

Medical examination Eksaminasyong Medikal
Before you start taking Drospirenone (Slinda) for the first time or if you re-start the treatment after some time of not taking it, your doctor will ask you some questions about your health and will do a complete physical examination, including blood pressure measurements. Your doctor will tell you how often you should go for control visits.
Bago ka magsimulang uminom ng Drospirenone (Slinda) sa kauna-unahang pagkakataon o kung nagsimula kang muli matapos mong ihinto ang paggamit nito, tatanungin ka ng doktor tungkol sa iyong kalusugan at gagawan ka ng kumpletong pisikal na eksaminasyon kasama rito ang pagsukat ng presyon ng iyong dugo. Sasabihin din sa iyo ng doktor kung gaano ka kadalas pupunta para sa kontroladong pagbisita.

Children and adolescents ***Mga Bata at Tinedyer***
Drospirenone (Slinda) is used after menarche (the first menstrual bleeding of a woman).
Ang Drospirenone (Slinda) ay ginagamit pagkatapos ng menarche (unang pagkakaroon ng buwanang dalaw ng isang babae).

Other medicines and Drospirenone (Slinda) ***Iba pang mga gamot at ang Drospirenone (Slinda)***
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. They can tell you if you need take additional contraceptive precautions (for example condoms) and if so, for how long, or whether the use of another medicine you need must be changed.
Ipagbigay alam sa iyong doktor o pharmacist kung ikaw ay umiinom, kakainom pa lamang o may iniinom na iba pang mga gamot. Masasabi nila kung kailangan mo pa ng karagdagang kontraseptibong pag-iingat (halimbawa, condom) at kung kailangan, gaano katagal o kung ang pag-inom mo ng ibang gamot ay kailangang baguhin.

Some medicines: *Mga ibang gamot:*
- can have an influence on the blood levels of Drospirenone (Slinda)
  ay maaaring maka-impluwensya sa antas ng Drospirenone sa dugo (Slinda)
- can make it less effective in preventing pregnancy
  maaaring gawin nitong mas hindi epektibo ang pagpigil sa pagbubuntis
- can cause unexpected bleeding *maaring magdulot ng hindi inaasahang pagdurugo*

These include medicines used for the treatment of:
Ang mga kasamang gamot na ginagamit na panlunas ay ang mga sumusunod:
- epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, felbamate, topiramate);
  epilepsy (hal. Primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, felbamate, topiramate);
- tuberculosis (e.g. rifampicin); *tuberculosis (hal. rifampicin);*
- HIV infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz);
  Mga impeksyong dulot ng HIV (hal. ritonavir, nelfinavir, nevirapine, efavirenz);
- Hepatitis C Virus infections (e.g. boceprevir, telaprevir);
  Mga impeksyong dulot ng Hepatitis C Virus (hal. boceprevir, telaprevir);
- other infections (griseofulvin); *Iba pang mga impeksyon (griseofulvin);*
- high blood pressure in the blood vessels in the lungs (bosentan);
  Mataas na presyon ng dugo sa daluyan nito sa baga (bosentan);
- depressive mood (the herbal remedy St. John's wort);
  pagkalungkot ng sarili (ang herbal na panglunas St. John's Wort);
- certain bacterial infections (e.g. clarithromycin, erythromycin);
  Iba pang impeksyon sanhi ng bakterya (hal. clarithromycin, erythromycin);
- fungal infections (e.g. fluconazole, itraconazole, ketoconazole, voriconazole);
  Impeksyon sanhi ng fungi (hal, fluconazole, itraconazole, ketoconazole, voriconazole);
- high blood pressure (hypertension), angina or certain heart rhythm disorders (e.g. diltiazem)
  Mataas na presyon ng dugo (hypertension), angina o iba pang sakit na may kinalaman sa problema sa ritmo at pagtibok ng puso (hal. diltiazem)

If you are taking medicines in a short-term treatment that might make Drospirenone (Slinda) less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Drospirenone (Slinda) may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long. Your doctor can tell you if you need to take additional contraceptive precautions and if so, for how long. If you are taking medicines or herbal products beyond the end of the white active tablets, discard the green placebo tablets and start the next pack right away.
Kung umiinom ka ng gamot nang pandalian lamang, maaari nitong mabawasan ang epekto ng Drospirenone (Slinda), kaya maaring gumamit ka ng pangharang na kontraseptib. Dahil ang epekto ng ibang gamot sa Drospirenone (Slinda) ay maaaring tumagal ng hanggang 28 araw matapos itigil ang pag-inom ng gamot, kailangan ng karagdagang paraan ng kontraseptib ng ganoong katagal. Maaaring magbigay ng payo sa iyo ang iyong doktor kung kailangan mo ng karagdagang kontraseptib at kung hanggang kailan. Kung umiinom ka ng gamot o produktong herbal nang lampas sa huli mong pag-inom ng puting tabletas, itapon na ang berdeng tabletas na placebo at simulan na kaagad ang kasunod na pakete.

If you are taking medicines in a long-term treatment that might make Drospirenone (Slinda) less effective, your doctor may advise you to use a non-hormonal method of birth control.
Kung umiinom ka ng gamot na pangmatagalan naman na maaring makabawas sa epekto ng Drospirenone (Slinda) maaaring payuhan ka ng doktor na gumamit ng hindi hormonal na pampigil sa pagbubuntis.

Drospirenone (Slinda) may also interfere with how other medicines work e.g:
Maaari ring makaapekto ang Drospirenone (Slinda) sa bisa ng iba pang mga gamot, hal:
- ciclosporine used to prevent rejection of transplanted organs (the effect may be increased)
  ciclosporine na ginagamit na pigilan ang hindi pagtanggap ng organong inilipat (maaring tumaas ang epekto)
- lamotrigine used for epilepsy (the effect may be decreased)
  lamotrigine na ginagamit sa epilepsy (maaring bumaba ang epekto)
- certain diuretics (aldosterone antagonists, potassium-sparing diuretics).Your doctor may recommend a blood test to check potassium levels during the first treatment cycle with Drospirenone (Slinda).
  Iba pang pampaihi (aldosterone antagonists, potassium-sparing diuretics). Maaaring magrekomenda ang iyong doktor ng pagsusuri sa dugo upang makita ang antas ng potassium sa unang siklo ng paglunas gamit ang Drospirenone (Slinda).

Drospirenone (Slinda) with food and drink ***Drospirenone (Slinda) kasama ng pagkain at inumin***
Avoid grapefruit or grapefruit juice while you are taking Drospirenone (Slinda).
Iwasan ang grapefruit o ang katas nito habang umiinom ka ng Drospirenone (Slinda)

Pregnancy and breast-feeding ***Pagbubuntis at Pagpapasuso***
Pregnancy Pagbubuntis
Do not use Drospirenone (Slinda) if you are pregnant, or think you may be pregnant. Use of Drospirenone (Slinda) prior or during pregnancy has not shown to increase risk of birth defects. However, undesirable effects cannot be excluded.
Huwag uminom ng Drospirenone (Slinda) kung ikaw ay nagdadalangtao o sa palagay mo ay buntis ka. Ang paggamit ng Drospirenone (Slinda) bago o habang nagdadalangtao ay hindi nagpakita na magkaroon ng mataas na panganib o depekto sa sanggol (birth defects). Subalit may mga hindi kaaya-ayang epekto na hindi maiiwasan.

Breast-feeding Pagpapasuso
Drospirenone (Slinda) may be used while you are breast-feeding. No effects on the breastfed newborns/infants are anticipated. However, very small amounts of drospirenone are excreted in the breast milk.
Ang Drospirenone (Slinda) ay maaaring inumin habang nagpapasuso.Walang epekto sa mga bagong silang na sanggol ang sadyang inaasahan. Subalit napakaunti lamang porsyento ng Drospirenone (Slinda) ang makikita sa gatas ng ina.

Driving and using machines ***Pagmamaneho at Paggamit ng mga Makina***
No effects on ability to drive and use machines are observed in users of oral hormonal contraceptives, although no studies have been performed with Drospirenone (Slinda).
Wala namang epekto sa kakayahang magmaneho at gumamit ng makina ang naobserbahan sa mga gumagamit ng kontraseptibong iniinom (oral) pero wala rin namang pag-aaral na naisagawa na sa Drospirenone (Slinda)

Drospirenone (Slinda) contains lactose ***Lactose na nasa Drospirenone (Slinda)***
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Kung sinabihan ka ng iyong doktor na mahina ang iyong kakayahan sa ibang sugars, kontakin ang iyong doktor bago ka uminom nitong gamot na ito.

Regular check-ups ***Regular na Konsulta***
When you are using Drospirenone (Slinda), your doctor will tell you to return for regular check-ups. In general, the frequency and nature of these check-ups will depend on your personal situation.
Sasabihan ka ng iyong doktor na regular na magpakonsulta kung gumagamit ka ng Drospirenone (Slinda). Sa pangkalahatan, ang dalas at uri ng mga konsultasyong ito ay nakabatay sa pansariling sitwasyon.

Contact your doctor as soon as possible if: Kumonsulta sa iyong doktor sa lalong madaling panahon kung:
- you have severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a thrombosis);
  may nararamdaman kang matinding kirot sa kaliwa o kanan mong binti, hindi maipaliwanag na kirot sa dibdib, kinakapos ng paghinga, hindi karaniwang ubo lalo na kung may kasamang dugo (maaaring nagpapakita ng thrombosis).
- you have a sudden, severe stomach ache or look jaundiced (you may notice yellowing of the skin and the whites of the eyes or dark urine, possibly indicating liver problems);
  mayroon kang biglaan at matinding sakit ng tiyan o naninilaw ka (mapapansin ang paninilaw ng balat at sa puti ng mata o maitim na ihi na nagpapakita ng may posibleng problema sa atay)
- you feel a lump in your breast (possibly indicating breast cancer);
  may nakakapa kang bukol sa iyong suso (maaaring nagpapahiwatig ng kanser sa suso)
- you have a sudden or severe pain in the lower abdomen or stomach area (possibly indicating an ectopic pregnancy, this is a pregnancy outside the womb);
  may biglaan at matinding kirot sa ibabang bahagi ng iyong tiyan (maaaring nagpapahiwatig ng pagbubuntis sa labas ng matres (ectopic pregnancy))
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
  kailangang hindi ka gagalaw o ma-ooperahan ka (Kumonsulta sa iyong doktor ng hindi baba sa apat na linggo o isang buwan bago pa ang operasyon);
- you have unusual, heavy vaginal bleeding;
  May hindi pangkaraniwang pagdurugo sa pwerta o ari ng babae;
- you suspect that you are pregnant.
  May kutob ka na ikaw ay nagdadalangtao o buntis.

3. How to take Drospirenone (Slinda) ***Paano mo iinumin ang Drospirenone (Slinda)***
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Palaging inumin ang gamot ayon sa sinabi ng iyong doktor. Siguruhin ito sa iyong doktor o pharmacist.

Each blister of Drospirenone (Slinda) contains 24 white active tablets and 4 green placebo tablets. The two differently coloured tablets are arranged in order.
Ang isang banig ng Drospirenone (Slinda) ay naglalaman ng 24 na kulay puting aktibong tabletas kasama ang apat na kulay berdeng plasibong tabletas. Nakahanay ng maayos ang dalawang uri ng may kulay na tabletas.

Take one tablet of Drospirenone (Slinda) every day with a little water if necessary. You may take the tablets with or without food (See section "Drospirenone (Slinda) with food and drink"). You must take the tablets everyday around the same time of the day so that the interval between two tablets is always 24 hours.
Uminom ng isang tableta ng Drospirenone (Slinda) araw-araw kasabay ng kaunting tubig kung kailangan. Maaari mo itong inumin ng may laman ang tiyan o wala (Tingnan ang seksyon: (Drospirenone (Slinda) na may pagkain at inumin") Kailangan mong inumin ang tableta araw-araw sa kaparehong oras para ang pagitan ng iyong pag-inom sa bawat araw ay palaging 24 na oras.

Do not confuse the tablets: Because of the different composition of the tablets it is necessary to begin with the first white tablet on the upper left and to take the tablets every day. For the correct order, follow the direction of the arrows and the sequence of numbers on the blister.
Huwag malilito sa tabletas: *Dahil sa iba't-ibang komposisyon ng tableta, kailangan na magsimula ka sa puting tableta na nakamarka sa kaliwang panig at inumin ito araw-araw. Para sa tamang pagkakasunod-sunod, sundin ang direksyon ng mga arrow at ng magkakasunod na bilang sa banig.*

The first tablet of the treatment should be taken on the first day of menstrual bleeding.
Thereafter tablet taking is continous. Take a white active tablet for the first 24 days and then a green placebo tablet for the last 4 days. You must then start a new pack straightaway without a break in daily tablet intake. There is therefore no gap between two packs.
Ang unang tableta sa gamutan ay kailangang inumin sa unang araw pa lang ng pagreregla. Pagkatapos nito, ang pag-inom ng tableta ay kailangang tuloy-tuloy. Uminom ng puting tableta sa unang 24 na araw at pagkatapos ay isunod ang apat na may berdeng tabletas na plasibo nang walang palya. Pagkatapos ay magsimula uling inumin ang nasa bagong pakete. Samakatuwid, tuloy-tuloy lang ang pag-inom sa pagitan ng dalawang pakete.

You may have some bleedings during the use of Drospirenone (Slinda), or you may also have no bleeding at all, but you must continue to take your tablets as normal without interruption.
If you use Drospirenone (Slinda) in this manner, you are protected against pregnancy also during the 4 days when you are taking a placebo tablet.
Maaaring magkaroon ka ng kaunting pagdurugo habang umiinom ka ng Drospirenone (Slinda), o maaari rin namang walang pagdurugo. Pero tuloy-tuloy mo lamang inumin ng walang pagtigil. Kung iinumin mo ang Drospirenone (Slinda) sa ganitong paraan, mapipigilan ka sa iyong pagbubuntis kahit pa apat na araw ka pang umiinom ng plasibo na tableta .

Preparation of the blister ***Paghahanda ng Banig***
To help you keep track, 7 week stickers each with the 7 days of the week are provided into the pack. Choose the week sticker that starts with the day you begin taking the tablets (for example, if you start on a Thursday, use the week sticker that starts with "THR") and place it on the blister card over the words "Place day label here" so that the first day is above the tablet marked "START". There is now a day indicated above every tablet and you can see whether you have taken a certain pill. The arrows and the consecutive numbers show the order you are to take the pills.
Para mas matulungan ka sa regular na pag-inom, may kasamang 7 sticker ang pakete para sa bawat isang araw sa buong isang linggo. Piliin ang sticker para sa linggo na nagsimula ka sa araw na iyon. Halimbawa, araw ng Huwebes ka nagsimulang uminom, gamitin ang linggunhang sticker na ang nagsisimula sa "THR"at ilagay ito sa blister card na may nakasulat na "Ilagay ang araw dito"para ang unang araw ay makikita mo sa itaas ng tableta na may markang "SIMULA". Mayroon na ngayong araw na nakasulat sa itaas ng tableta para makita mo kung nakainom ka na ng nararapat na tableta. Ang arrow at mga sunod-sunod na mga bilang ay nagpapakita ng pagkakasunodsunod ng mga pildoras.

Starting your first pack of Drospirenone (Slinda) ***Pagsisimula ng unang pakete ng Drospirenone (Slinda)***
- *If you have not used a hormonal contraceptive in the previous month Kung hindi ka pa nakagamit ng kontraseptibong hormonal ng mga nakalipas na buwan*

Begin with Drospirenone (Slinda) on the first day of your period. When doing so, you are immediately protected against pregnancy and you do not need to use extra protective measures such as a condom.
Magsimula ng Drospirenone (Slinda) sa unang araw ng iyong buwanang dalaw. Kapag ginawa mo ito, tiyak na mabilis na mapipigilan ang iyong pagbubuntis at hindi mo na kailangan pang gumamit ng karagdagang proteksyon tulad ng condom.
- *When changing from a combined pill, vaginal ring or transdermal patch Kung magpapalit mula sa combined pill, vaginal ring o transdermal patch*

You should start Drospirenone (Slinda) on the day after the last active tablet (the last tablet containing the active substances) of your previous pill or on the day of removal of your vaginal ring or transdermal patch (this means no tablet-, ring- or patch-free break). If you follow these instructions, additional contraceptive precautions are not necessary.
Maaari ka ring magsimula ng Drospirenone (Slinda) sa araw pagkatapos ng huling aktibong tableta (huling tableta na may aktibong sangkap) ng dati mo pang iniinom na gamot o sa araw na tinanggal ang iyong vaginal ring o transdermal patch (ibig sabihin, walang tablet-, ring-, o patch-free break). Kung susundin mo ang panuntunan, hindi mo na kakailanganin ng karagdagang kontraseptib.
You can also start Drospirenone (Slinda) at the latest on the day following the usual tablet-, ring-, patch-free break or placebo interval of your previous contraceptive. In this case, make sure you use an additional barrier method of contraception for the first 7 days of Drospirenone (Slinda) taking.
Maaari ka ring magsimula ng Drospirenone (Slinda) sa huling araw kasunod ng dati mo pang tablet, ring, patch-free break o interval ng plasibo mula sa dati mo pang kontraseptib. Sa ganitong kaso, siguruhin na gagamit ka ng dagdag na pampigil sa pagbubuntis sa buong unang ika-pitong araw ng pag-inom mo ng Drospironone (Slinda).
- *When changing from another progestogen-only pill (POP) Kung magpapalit ka mula sa ibang progestogen-only pill (POP)*

You may switch any day from other POP and start taking Drospirenone (Slinda) the next day. Additional contraceptive precautions are not necessary.
Maaari kang lumipat anumang araw mula sa ibang POP at magsimula kang uminom ng Drospirenone (Slinda) sa susunod na araw. Walang karagdagang pag-iingat na kontraseptibo ang kinakailangan.
- *When changing from a progestogen-only- injection or implant or from a progestogen-releasing intrauterine system (IUS) Kapag nagpapalit mula sa progestogen lamang na iniksyon o implant o mula sa progestogen -releasing intrauterine system (IUS)*

You should start Drospirenone (Slinda) the day when the next injection is due or on the day that your implant or your IUS is removed. Additional contraceptive precautions are not necessary.
Kailangan mong magsimula ng Drosperinone (Slinda) sa araw ng sunod na iniksyon o doon sa araw na aalisin na ang iyong implant o intrauterine system. Walang karagdagang pag-iingat na kontraseptibo ang kinakailangan.
- *After having a baby Pagkatapos makapanganak*

You can start Drospirenone (Slinda) any day between day 21 to 28 after having your baby. If you start later than day 28 but before the menstruation have returned, you must be sure that you are not pregnant and you must use a barrier method as a condom until you have completed the first 7 days of tablet-taking.
Maaari kang magsimula anumang araw sa pagitan ng 21 hanggang 28 araw pagkatapos mong makapanganak. Kung magsimula ka ng lampas sa 28 araw pero bago pa bumalik ang buwanang regla, kailangang makatiyak na hindi ka buntis at kailangan mong gumamit ng pampigil sa paraan (barrier method) tulad ng condom hanggang sa makumpleto mo ang unang pitong araw ng pag-inom mo ng mga tableta.
Information for breast-feeding women can be found in section 2 (Pregnancy and breast-feeding).
Ang mga impormasyon para sa mga nagpapasusong ina ay matatagpuan sa Seksyon 2 (Pagbubuntis at Pagpapasuso).
- *After miscarriage or an abortion Pagkatapos makunan o aborsyon*

You should follow the advice of your doctor.
Kailangang sundin mo ang payo ng iyong doktor.

Ask your doctor if you are still not sure when to start. *Tanungin mo rin ang iyong doktor kung hindi ka sigurado kung kailan ka dapat magsimula.*

If you take more Drospirenone (Slinda) than you should ***Kung nakainom ka ng maraming Drospirenone at salungat sa dapat na bilang***
There have been no reports of serious harmful effects from taking too many Drospirenone (Slinda) tablets at one time. Symptoms that may occur are nausea, vomiting and slight vaginal bleeding. However, in case of overdose, ask your doctor for advice because blood tests should be done.
Wala namang masamang naiulat na seryoso at masamang epekto sa pag-inom ng marami nitong Drospirenone (Slinda). Ang mga sintomas na maaaring makita ay ang pagkahilo, pagsusuka at bahagyang pagdurugo ng pwerta o ari ng babae. Ngunit kung sakaling masobrahan ka ng ininom, kumonsulta sa iyong doktor sakaling kailanganin ang pagsusuri ng dugo.

If you forget to take Drospirenone (Slinda) ***Kung makalimutan ang pag-inom ng Drospirenone (Slinda)***
You must take the tablets everyday around the same time of the day so that the interval between two tablets is always 24 hours. If you are less than 24 hours late in taking any single tablet, take the missed tablet as soon as it is remembered and take the next tablet at the usual time, even if this means taking two tablets at the same time. If you are more than 24 hours late in taking any white active tablet, take the missed tablet as soon as it is remembered, even if this means taking two tablets at the same time, and use an additional method of contraception (such as a condom) for the next 7 days. Then, continue taking the tablets at your usual time. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased.
Kailangan mong inumin ang tableta araw-araw sa kaparehong oras para ang pagitan ng iyong pag-inom sa bawat araw ay palaging 24 oras. Kung nahuli ka sa iyong pag-inom ng isang anumang tableta ng hindi lalagpas ng 24 oras, inumin mo kaagad ang tabletang iyon at sundan ito ng kasunod na tableta sa parehong dating oras ng pag-inom, kahit na kakailanganin mong uminom ng dalawang tableta ng magkasabay. Kung nahuli ka sa iyong pag-inom ng puting aktibong tableta ng lagpas ng 24 oras, inumin mo kaagad ang tabletang iyon at sundan ito ng kasunod na tableta sa parehong dating oras ng pag-inom, kahit na kakailanganin mong uminom ng dalawang tableta ng magkasabay, at gumamit ng dagdag na paraan ng kontrasepsyon (tulad ng condom) para sa susunod na pitong (7) araw. Patuloy na inumin ang mga tableta sa parehong dating oras ng pag-inom. Mas maraming sunod-sunod na araw na hindi ka nakainom, mas mataas din ang panganib na mabawasan ang bisa ng kontraseptib.

If you have forgotten a tablet in the first week starting the tablets, and you have had sex in the week before forgetting the tablet you must realize that there is a risk of pregnancy. In that case, contact your doctor.
Kung nakalimutan mong uminom ng tableta sa unang linggo na umiinom ka nito at nakipagtalik ka sa linggong iyon bago mo ito nakalimutan, dapat mong maisip na may panganib na mabuntis ka sa linggong iyon. Sa ganitong kaso, kumonsulta sa iyong doktor.

If you forgot to take the tablet **between days 15 - 24 (third or fourth row),** take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the white active tablets at the usual time. Instead of taking the green placebo tablets on this strip, throw them away, and start the next strip (the starting day will be different). By skipping the placebo interval, the contraceptive protection is maintained.The last 4 green tablets in the **4th row** of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of Drospirenone (Slinda). Throw away the forgotten placebo tablet.
Kung nakalimutan mong uminom ng tableta ***sa pagitan ng araw 15-24 (ikatlo at ikaapat na hanay)*** *inumin mo ang nakalimutan mong tableta kaagad na maalala mo kahit pa iinom ka ng dalawang tableta sa parehong oras. Ipagpatuloy mo ang pag-inom ng aktibong tableta sa magkakaparehong oras. Pero itapon mo ang berdeng kulay na plasibo sa naturang banig at magsimula ka na sa bagong banig (magkaiba ang simulang araw). Sa paglaktaw mo sa interval ng plasibo, mapapanatili pa rin ang bisa ng proteksyon ng kontraseptib. Ang huling kulay berdeng tabletas na nasa* ***ikaapat na hanay*** *ang mga plasibong tabletas. Kung makalimutan mong inumin ang isa sa mga ito, wala naman itong epekto sa bisa ng Drospirenone (Slinda). Itapon na lang ang nakalimutan mong inumin na plasibong tabletas.*

What to do in the case of vomiting or severe diarrhea ***Ano ang dapat gawin sa kaso ng pagsusuka at matinding pagtatae?***
If you vomit or have severe diarrhea, there is a risk that the active substance in the pill will not be fully absorbed by your body, the situation is almost the same as forgetting a tablet. In these cases, an additional method of contraception may be needed, ask your doctor for advice.
Kung nagsuka o may matinding pagtatae, may panganib na ang aktibong sangkap sa pildoras ay hindi buong naipasok sa iyong katawan. Ang sitwasyong ito ay maihahalintulad din sa pagkalimot ng pag-inom ng tableta. Sa mga ganitong kaso, karagdagang paraan ng kontrasepsyon ay kakailanganin kaya humingi ka ng payo sa iyong doktor.

If you vomit or have severe diarrhea within 3-4 hours after taking your white active tablet of Drospirenone (Slinda), you must take another white tablet from another blister pack as soon as possible. If possible, take it within 24 hours of when you normally take your pill. Additional contraceptive precautions are not necessary. If this is not possible or 24 hours have passed, you should follow the advice given in the section "If you forget to take Drospirenone (Slinda)" above.

Kung nagsuka o nagkaroon ng matinding pagtatae sa loob ng tatlo hanggang apat na oras pagkatapos inumin ang kulay puting tableta na may aktibong sangkap ng Drospirenone (Slinda), kailangan mong uminom kaagad uli ng isa pang kulay puti na tableta galing sa iba namang banig. Kung maaari, inumin mo ito sa loob ng 24 oras kung kailan ka palaging umiinom nito. Hindi na kailangan ng karagdagang paraan ng kontrasepsyon. Kung hindi ito maaring mangyari, o 24 oras na ang nakalipas, kailangan mong sundin ang payo na nakasaad sa section "Kung nakalimutan mong uminom ng Drospirenone (Slinda)" na nasa itaas.

If you stop taking Drospirenone (Slinda) ***Kung huminto ka sa pag-inom ng Drospirenone (Slinda)***
You can stop taking Drospirenone (Slinda) whenever you want. From the day you stop you are no longer protected against pregnancy. If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.
Maari kang huminto sa pag-inom ng Drospirenone (Slinda) anumang oras na iyong gustuhin. Mula sa araw na huminto ka ay hindi ka na protektado sa pagbubuntis. Kung may iba ka pang katanungan sa paggamit ng gamot, tanungin mo ang iyong doktor, pharmacist o nars.

4. Possible side effects ***Mga posibleng masamang epekto sa katawan***
Like all medicines, Drospirenone (Slinda) can cause side effects, although not everybody get them. Serious undesirable effects associated with the use of Drospirenone (Slinda) are described in the paragraphs 'Breast cancer' and 'Thrombosis' in section 2 'What you need to know before you take Drospirenone (Slinda)'. Please read this section for additional information and consult your doctor at once where appropriate.
Tulad din ng ibang gamot, ang Drospirenone (Slinda) ay maaaring magdulot ng ibang mga epekto pero hindi naman lahat ay nagkakaroon nito. Seryosong hindi kaaya-ayang epektong maaaring iugnay sa paggamit ng Drospirenone (Slinda) ay isinalarawan sa mga talatang "Kanser sa suso" at "Thrombosis" sa seksyon 2. Ano ang kailangan mong malaman bago ka uminom ng Drospirenone (Slinda). Pakibasa ang seksyon para sa karagdagang impormasyon at kumonsulta sa inyong doktor kaagad kung naaangkop.

Vaginal bleeding may occur at irregular intervals during the use of Drospirenone (Slinda). This may be just slight staining which may not even require a pad, or heavier bleeding, which look rather like a scanty period and requires sanitary protection. You may also not have any bleeding at all. The irregular bleedings are not a sign that the contraceptive protection of Drospirenone (Slinda) is decreased. In general, you need not take any action; just continue to take Drospirenone (Slinda). If, however, bleeding is heavy or prolonged you should consult your doctor.
Ang hindi regular o manaka-nakang pagdurugo ng pwerta ay maaaring maranasan habang umiinom ng Drospirenone (Slinda). Maaari itong isang maliit na mantsa na hindi kailangan ng pasador o yung malakas na pagdurugo na parang tulad sa patak patak na buwanang dalaw at kailangan ding gamitan ng pasador o napkin. Maaari rin namang walang anumang pagdurugo. Ang hindi regular o manaka-nakang pagdurugo ay hindi senyales na ang bisa ng Drospirenone (Slinda) ay nabawasan. Sa pangkahalatan, maaaring wala ka namang gawing aksyon bagkus ipagpatuloy mo lang ang pag-inom ng Drospirenone (Slinda). Ngunit, kung masyadong malakas ang pagdurugo at pangmatagalan, kailangan mo nang konsultahin ang iyong doktor.

If the bleeding is very frequent and irregular, another contraceptive method should be considered. If you don't have vaginal bleeding during the treatment, you may need to do a pregnancy test if you have not taken the tablets in accordance with the instructions in section 3 "How to take Drospirenone (Slinda)".
Kung ang pagdurugo ay masyado ng malimit at panaka-naka, baka kailangan mo na ng ibang paraan ng kontraseptib. Kung wala namang pagdurugo sa iyong pwerta habang ginagamit ito, kailangan mong magpasuri para sa pagbubuntis kung hindi ka nakainom ng tableta ayon sa panuntunan na nasa Seksyon 3 "Paano inumin ang Drospirenone (Slinda)".

The following side effects have been associated with the use of Drospirenone (Slinda): *Ang ibang mga epekto sa katawan na naiuugnay sa paggamit ng Drospirenone (Slinda) ay ang mga sumusunod:*
Common: may affect up to 1 in 10 people Karaniwan: may epekto sa 1 hanggang 10 katao
- headache *sakit ng ulo*
- nausea, abdominal pain *pagkaalibadbad, sakit ng tiyan*
- changes in sexual desire, altered mood
  pagbabago sa pagkagustong sekswal, pagbabago ng mood
- acne *acne*
- breast discomfort, painful periods, bleeding and irregular menstrual periods *may kirot na nararamdaman sa suso, masakit at hindi regular na buwanang dalaw*
- weight gain *pagtaas ng timbang*

Uncommon: may affect up to 1 in 100 people Hind karaniwan: may epekto sa 1 hanggang 100 katao
- anaemia (decreased number of the red blood cells), fatigue (tiredness), fluid retention
  anaemia (pagkabawas ng bilang ng selyula ng pulang dugo), pagkapagod (pagkapagal), pananatili ng likido sa katawan
- dizziness, *pagkahilo,*
- vomiting, diarrhea, constipation *pagsusuka, pagtatae, pagtitibi*
- vaginal infections *impeksyon sa pwerta o ari ng babae*
- increased amount of the following, shown in blood tests: potassium, liver enzymes (ALT, AST, GGT), bilirubin, creatine phosphokinase, triglycerides
  mataas na antas ng mga sumusunod na nakita sa pagsusuri ng dugo: potassium, enzymes sa liver (ALT, GGT) bilirubin, creatine phosphokinase, triglycerides
- appetite changes *pagbabago sa ganang kumain*
- uterine leiomyoma (benign tumor of the uterus) *uterine leiomyoma (benign tumor sa matres)*
- depressed mood, depression, anxiety *pagkamalungkutin, depresyon, pagkabalisa*
- absence of menstrual periods, altered menstrual bleeding, pelvic pain, ovarian cysts, vaginal discharge and dryness
  walang buwanang dalaw, naiba ang iskedyul ng buwanang dalaw, may kirot sa sasapnan, bukol sa obaryo, may likidong lumalabas sa pwerta at panunuyo
- hair loss, increased sweating, itching, rash, seborrhoea (greasy skin), dermatitis (inflammation of the skin)
  pagkalagas ng buhok, mas pinagpapawisan, pangangati, pamamantal, seborrhoea (malangis na balat), dermatitis (pamamaga sa balat)
- elevated blood pressure, hot flushes *mataas na presyon ng dugo, mainit na hulab sa sarili (hot flashes)*
- hypersensitivity *hypersensitivity*

Rare: may affect up to 1 in 1,000 people: Bihira: may epekto sa 1 hanggang 1000 katao:
- contact lens intolerance *hindi kayang magcontact lens*
- weight loss *pagkabawas ng timbang*
- excessive amount of urine *masyadong maraming umihi*
- breast cyst, breast secretion, abnormal cervical smear, genital itching *may bukol sa suso, may tumatagas sa suso, hindi normal na cervical smear, pangangati ng ari*

Reporting of side effects ***Pag-uulat ng ibang mga epekto sa katawan***
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.
Kung makaranas kayo ng ibang mga epekto sa katawan, kumonsulta sa inyong doktor o pharmacist. Kasama rito ang mga ibang posibleng epekto na hindi nakalista sa babasahing ito. Sa pag-uulat ninyo ng ibang mga epekto sa katawan makakatulong kayo na makapagbigay ng impormasyon tungkol sa pagiging ligtas ng gamot na ito.

5. How to store Drospirenone (Slinda) ***Paano itatago ang Drospirenone (Slinda)***
Keep this medicine out of the sight and reach of children.
Itago ang gamot na ito sa lugar na hindi makikita at maaabot ng mga bata

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
Huwag gagamitin ang gamot kung lampas na sa petsa na nakasaad sa itaas ng kahon at blister o EXP. Ang petsa na ito ay tuwing ikahuling araw ng naturang buwan.

Store at temperatures not exceeding 30 ºC.
Itago o ilagay sa lugar na may temperaturang hindi lalampas sa 30 ºC.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
Huwag itapon ang gamot sa daanan ng tubig o kasama ng mga basurang pambahay. Itanong sa pharmacist kung paano itatapon ang mga gamot na hindi mo nainom. Isa itong paraan para maprotektahan ang ating kapaligiran.

6. Contents of the pack and other information ***Mga nilalaman ng pakete at iba pang impormasyon***
What Drospirenone (Slinda) contains ***Ang Drospirenone (Slinda) ay naglalaman ng***
White active film-coated tablets: Puting aktibong tableta na binalutan ng film
- The active substance is drospirenone. Each white active film-coated tablet contains 4 mg of drospirenone. *Ang aktibong sangkap ay drospirenone. Ang bawat puting aktibong tableta ay naglalaman ng 4 mg drospirenone.*

Tablet core: microcrystalline cellulose; lactose; silica, colloidal (E551); magnesium stearate (E470b)
Tablet coat: polyvinyl alcohol; titanium dioxide (E171); Macrogol; talc (E553b)

Green placebo film-coated tablets: Berdeng plasibong tableta na binalutan ng film:
- The green placebo film-coated tablets do not contain active substance. *Ang berdeng plasibong tableta ay hindi naglalaman ng aktibong sangkap*

Tablet core: lactose monohydrate; maize starch; povidone; silica, colloidal (E551); magnesium stearate (E470b)
Tablet coat: hypromellose (E464); triacetin; polysorbate 80 (E433); titanium dioxide (E171); Indigo carmine aluminium lake (E132); yellow iron oxide (E172)

What Drospirenone (Slinda) looks like and contents of the pack
Each blister of Drospirenone (Slinda) contains 24 active film-coated tablets and 4 placebo film-coated tablets.
Ang isang banig ng Drospirenone (Slinda) ay naglalaman ng 24 na aktibong tabletang nababalot ng film at apat na tabletang plasibo na nababalot din ng film.

The active tablet is a round, white tablet with the letters "E" and "D" debossed on opposite sides, with a diameter of 5 mm.
Ang aktibong tableta ay bilog, kulay puti na may letrang "E" at "D" na nakaukit sa magkabilang bahagi at may dayametrong 5 mm.

The placebo tablet is a round, green tablet with the letter "E" and the number "4" debossed on opposite sides, with a diameter of 5 mm.
Ang plasibong tableta ay bilog, kulay berdeng tableta na may letrang "E" at numerong "4" na nakaukit sa magkabilang bahagi na may dayametrong 5 mm.

In addition to the carton box, a carton case for the blister is enclosed.
Bukod pa sa kahon nito, ang pinakalalagyang karton ay nakalakip din dito.

Drospirenone (Slinda) is available in calendar-packs of 1 blister each with 28 tablets.
Ang Drospirenone (Slinda) ay makukuha sa calendar packs na isang banig na mayroong 28 tabletas.

Caution ***Babala:***
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.
Ang Foods, Drugs, Devices at Cosmetics Act ay nagbabawal na magbigay ng gamot nang walang reseta.

Adverse Drug Reaction ***Masamang Reaksyon sa Gamot***
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of any adverse drug reaction.
Para sa mga pinaghihinalaang reaksyon sa gamot, iulat ito sa FDA, www.fda.gov.ph
Kaagad na humanap ng atensyong medikal sa unang senyales pa lamang ng masamang reaksyon mula sa gamot.

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Manufactured by: *Ginawa ng:*
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Embil

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Drospirenone

Slinda

4mg Film-Coated Tablet
Hormonal Contraceptive

Rx

1. NAME OF THE MEDICINAL PRODUCT
Drospirenone (Slinda) 4 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
White active film-coated tablets: Each tablet contains 4 mg of drospirenone.
Green placebo film-coated tablets: The tablet does not contain active substances.
Excipient with known effect:
Each white active film-coated tablet contains 17.5 mg of lactose.
Each green placebo film-coated tablet contains 52.7 mg of lactose (as monohydrate), equivalent to 55.5 mg of lactose monohydrate
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Film-coated Tablet
The active tablet is a round, white tablet with the letters "E" and "D" debossed on opposite sides, with a diameter of 5 mm.
The placebo tablet is a round, green tablet with the letter "E" and the number "4" debossed on opposite sides, with a diameter of 5 mm.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Hormonal contraceptive

4.2 Dosage and method of administration
4.2.1 Method of administration
Oral use

4.2.2 Dosage regimen
How to take Drospirenone (Slinda)
One tablet is to be taken daily for 28 consecutive days, one white active tablet daily during the first 24 days and one green inactive tablet daily during the 4 following days. Tablets must be taken every day at about the same time of the day so that the interval between two tablets is always 24 hours. Tablets should be taken in the order shown on the blister. Stickers marked with the 7 days of the week are provided. The woman should choose the sticker that starts with the day she begins taking the tablets and stick it on the blister.

The first tablet of the treatment should be taken on the first day of menstrual bleeding. Thereafter tablet taking is continuous. A subsequent pack is started immediately after finishing the previous pack, without a break in daily tablet intake.

How to start Drospirenone (Slinda)
- *No preceding hormonal contraceptive use (in the past month)*

Tablet-taking has to start on day 1 of the woman's natural cycle (first day of her menstrual bleeding). When doing so, no additional contraceptive measures are necessary.

- *Following first-trimester abortion*

After first-trimester abortion it is recommended to start Drospirenone (Slinda) immediately after abortion took place. In that case there is no need to use an additional contraceptive method.

- *Following delivery or second-trimester abortion*

Contraceptive treatment with Drospirenone (Slinda) is recommended to start between 21 and 28 days after delivery or second trimester abortion. If contraceptive treatment with Drospirenone (Slinda) is initiated later but before the menstruations have returned, pregnancy must be ruled out and an additional method of contraception should be used for the first week.
For breast-feeding women, see section 4.6.

- *Changing from a combined hormonal contraceptive (combined oral contraceptive (COC), vaginal ring or transdermal patch)*

The woman should start Drospirenone (Slinda) preferably on the day after the last active tablet (the last tablet containing the active substances) of her previous COC or on the day of removal of her vaginal ring or transdermal patch. In these cases, the use of an additional contraceptive is not necessary.

The woman may also start Drospirenone (Slinda) at the latest on the day following the usual tablet-free, ring-free, patch-free or placebo tablet interval of her previous combined hormonal contraceptive, but during the first 7 days of tablet taking an additional barrier method is recommended.

- *Changing from a progestogen-only-method (progestogen-only pill (POP), injection, implant) or from a progestogen-releasing intrauterine system (IUS)*

The woman may switch any day from another POP and should start Drospirenone (Slinda) the day after, within 24 hours of discontinuing the previous POP. A woman may switch from an implant or following IUS removal on the same day that the implant or IUS is removed. A woman may switch from using an injectable contraceptive and should start Drospirenone (Slinda) on the day the next injection was due to occur. In all of these cases, the use of an additional contraceptive is not necessary.

Management of missed tablets
Tablets should be taken every 24 hours. If the woman is less than 24 hours late in taking any single tablet, contraceptive protection is not reduced. The woman should take the tablet as soon as she remembers and should take further tablets at the usual time.

If the user is more than 24 hours late in taking any white active tablet, contraceptive protection may be reduced and use of a barrier method such as a condom should be considered for the next 7 days. The missed tablet should be taken as soon as it is remembered, even if this means taking two tablets at the same time. She then continues to take tablets at her usual time.

If tablets were missed in the first week after initiation of Drospirenone (Slinda) and intercourse took place in the week before the tablets were missed, the possibility of a pregnancy should be considered.

If tablets were missed in the third week of pill taking, the risk of reduced reliability is imminent because of the forthcoming 4-day hormone-free interval. However, by adjusting the tablet-intake schedule, reduced contraceptive protection can still be prevented. The user should take the last missed tablet as soon as she remembers, even if this means taking two tablets at the same time. She then continues to take the active tablets at her usual time. The user is advised not to take the placebo pills and continue straight on to the next active blister pack.

Missed (green) placebo tablets can be disregarded. However, they should be discarded to avoid unintentionally prolonging the interval between active tablet taking.

Advice in case of gastrointestinal disturbances
In case of severe gastrointestinal disturbances (e.g., vomiting or diarrhea), absorption may not be complete and additional contraceptive measures should be taken.

If vomiting or diarrhea occurs within 3-4 hours after tablet taking, a new (replacement) tablet should be taken as soon as possible. The new tablet should be taken within 24 hours of the usual time of tablet-taking if possible. If more than 24 hours elapse, the advice concerning missed tablets, as given in Section 4.2 "Management of missed tablets", is applicable. If the woman does not want to change her normal tablet-taking schedule, she has to take the extra tablet(s) from another blister pack.

4.2.3 Additional information on special populations
Paediatric population
Safety and efficacy of Drospirenone (Slinda) have been established in women of reproductive age. Safety and efficacy are expected to be the same for post pubertal adolescents under the age of 18 and users 18 years and older. Use of this product before menarche is not indicated.

4.3 Contraindications
Progestogen-only contraceptives (POCs) like Drospirenone (Slinda) should not be used in the presence of any of the conditions listed below. Should any of the conditions appear for the first time during Drospirenone (Slinda) use, the medicinal product should be discontinued immediately.

- Active venous thromboembolic disorder.
- Presence or history of severe hepatic disease as long as liver function values have not returned to normal.
- Severe renal insufficiency or acute renal failure.
- Adrenal insufficiency
- Known or suspected sex-steroid sensitive malignancies.
- Undiagnosed vaginal bleeding.
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use
If any of the conditions/risk factors mentioned below is present, the benefits of Drospirenone (Slinda) should be weighed against the possible risks for each individual woman and discussed with the woman before she decides to start using Drospirenone (Slinda). In the event of aggravation, exacerbation or first appearance of any of these conditions, the woman should contact her physician. The physician should then decide whether Drospirenone (Slinda) use should be discontinued.

Hyperkalemia
Drospirenone is an aldosterone antagonist with potassium sparing properties. In most cases, no increase of potassium levels is to be expected. However, it is recommended to check serum potassium levels during the first treatment cycle in women presenting with renal insufficiency and pre-treatment serum potassium in the upper reference range and during concomitant use of potassium sparing medicinal products (see section 4.5).

Circulatory disorders
From epidemiological studies there is little evidence for an association between progestogen-only preparations and an increased risk of myocardial infarction or cerebral thromboembolism. Rather, the risk of cardiovascular and cerebral events is related to increasing age, hypertension, and smoking. In women with hypertension the risk of stroke may be slightly enhanced by progestogen-only preparations.

Although not statistically significant, some studies indicate that there may be a slightly increased risk of venous thromboembolism (deep venous thrombosis, pulmonary embolism) associated with the use of progestogen-only preparations. Generally recognized risk factors for venous thromboembolism (VTE) include a positive personal or family history (VTE in a sibling or a parent at a relatively early age), age, obesity, prolonged immobilization, major surgery or major trauma.

Treatment should be stopped at once if there are symptoms of an arterial or venous thrombotic event or suspicion thereof and discontinuation of Drospirenone (Slinda) should be considered in case of prolonged immobilization due to surgery or illness.

Bone metabolism
Treatment with Drospirenone (Slinda) leads to decreased estradiol serum levels, to a level corresponding with the early follicular phase. It is currently unknown whether the decrease in estradiol serum levels may have a clinically relevant effect on bone mineral density. Loss of bone mineral density is of particular concern during adolescence and early adulthood, a critical period of bone accretion. It is unknown if bone mineral density decrease in this population will reduce peak bone mass and increase the risk for fracture in later life.

Breast Cancer
A meta-analysis from 54 epidemiological studies reported that there is a slightly increased relative risk (RR = 1.24) of having breast cancer diagnosed in women who are currently using oral contraceptives (OCs), mainly using estrogen-progestogen preparations. The excess risk gradually disappears during the course of the 10 years after cessation of combined OC (COC) use. Because breast cancer is rare in women under 40 years of age, the excess number of breast cancer diagnoses in current and recent COC users is small in relation to the overall risk of breast cancer. These studies do not provide evidence for causation. The observed pattern of increased risk may be due to an earlier diagnosis of breast cancer in OC users, the biological effects of OCs or a combination of both. The breast cancers diagnosed in users of OCs tend to be less advanced clinically than the cancers diagnosed in those who have never used OCs.

The risk of having breast cancer diagnosed in users of progestogen-only preparations is possibly of similar magnitude to that associated with COC. However, for progestogen-only preparations, the evidence is based on much smaller populations of users and so is less conclusive than that for COCs.

Other tumours
In rare cases, benign liver tumours, and even more rarely, malignant liver tumours have been reported in users of combined hormonal contraceptives. In isolated cases, these tumours have led to life-threatening intra-abdominal haemorrhages. A hepatic tumour should be considered in the differential diagnosis when severe upper abdominal pain, liver enlargement or signs of intra-abdominal haemorrhage occur.

Ectopic pregnancy
The protection with traditional progestogen-only pills against ectopic pregnancies is not as good as with combined oral contraceptives, which has been associated with the frequent occurrence of ovulations during the use of progestogen-only pills. Despite the fact that Drospirenone (Slinda) consistently inhibits ovulation ectopic pregnancy should be taken into account in the differential diagnosis if the woman presents amenorrhoea or abdominal pain

Liver function
Discontinue Drospirenone (Slinda) if jaundice develops. Steroid hormones may be poorly metabolized in patients with impaired liver function. Acute or chronic disturbances of liver function may require the discontinuation of Drospirenone (Slinda) use until markers of liver function return to normal and Drospirenone (Slinda) causation has been excluded.

Diabetes
Although progestogens may have an effect on peripheral insulin resistance and glucose tolerance, there is no evidence for a need to alter the therapeutic regimen in diabetics using POPs such as Drospirenone (Slinda). However, diabetic patients should be carefully observed during the first months of use. Special attention should be paid to diabetic patients with vascular involvement.

Other conditions
If a sustained hypertension develops during the use of Drospirenone (Slinda), or if a significant increase in blood pressure does not adequately respond to antihypertensive therapy, the discontinuation of Drospirenone (Slinda) should be considered.

Like with any other hormonal contraceptive, chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking Drospirenone (Slinda). Depressed mood and depression are well-known undesirable effects of hormonal contraceptive use (see section 4.8). Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. Women should be advised to contact their physician in case of mood changes and depressive symptoms, appearing shortly after initiation of the treatment.

The following conditions have been reported both during pregnancy and during sex steroid use, but an association with the use of progestogens has not been established: jaundice and/or pruritus related to cholestasis; gallstone formation; porphyria; systemic lupus erythematosus; haemolytic uraemic syndrome; Sydenham's chorea; herpes gestationis; otosclerosis-related hearing loss; (hereditary) angioedema.

Each white active tablet contains 17.50 mg of lactose and each green placebo tablet contains 52.7 mg of lactose (as monohydrate), equivalent to 55.50 mg of lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Medical examination/consultation
Prior to the initiation or reinstitution of Drospirenone (Slinda) a complete medical history (including family history) should be taken and pregnancy must be ruled out. Blood pressure should be measured, and a physical examination should be performed, guided by the contra-indications (see section 4.3) and warnings (see section 4.4). The woman should also be instructed to carefully read the user leaflet and to adhere to the advice given. The frequency and nature of examinations should be based on established practice guidelines and be adapted to the individual woman.

Women should be advised that oral contraceptives do not protect against HIV infections (AIDS) and other sexually transmitted diseases.

Changes in the menstrual bleeding pattern
Disruption of the menstrual bleeding pattern may occur during use of hormonal contraceptives that inhibit ovulation, including Drospirenone (Slinda) (see section 5.1).

If the bleeding is very frequent and irregular, another contraceptive method should be considered. If the symptoms persist, an organic cause should be ruled out. Management of amenorrhoea during treatment depends on whether or not the tablets have been taken in accordance with the instructions and may include a pregnancy test.

The treatment should be stopped if a pregnancy occurs.

Reduced efficacy
The efficacy of POPs may be reduced in the event of e.g. missed tablets (see section 4.2), gastro-intestinal disturbances (see section 4.2) or concomitant medication (see section 4.5).

Laboratory tests
The use of contraceptive steroids may influence the results of certain laboratory tests, including biochemical parameters of liver, thyroid, adrenal and renal function, serum levels of (carrier) proteins, e.g. corticosteroid binding globulin and lipid/lipoprotein fractions, parameters of carbohydrate metabolism and parameters of coagulation and fibrinolysis.

4.5 Interaction with other medicinal products and other forms of interaction
Influence of other medicinal products on Drospirenone (Slinda)
Interactions can occur between Drospirenone (Slinda) and other medicinal products that induce microsomal enzymes. This can result in increased clearance of sex hormones and may lead to breakthrough bleeding and/or contraceptive failure.

Management
Enzyme induction can already be observed after a few days of treatment. Maximum enzyme induction is generally seen within a few weeks. After drug therapy is discontinued, enzyme induction may be sustained for about 4 weeks.

Short-term treatment
Women on treatment with enzyme inducing drugs should temporarily use a barrier method or another method of contraception in addition to the POP. The barrier method must be used during the whole time of the concomitant drug therapy and for 28 days after its discontinuation.

If the drug therapy runs beyond the end of the active tablets in the POP pack, the placebo tablets must be discarded, and the next POP pack should be started right away.

Long-term treatment
In women on long-term treatment with enzyme-inducing active substances, another reliable, nonhormonal, method of contraception is recommended.

The following interactions have been reported in the literature (mainly with combined contraceptives but occasionally also with progestogen-only pills).

Substances increasing the clearance of contraceptive hormones (diminished contraceptive efficacy by enzyme induction) e.g.:
Barbiturates, bosentan, carbamazepine, phenytoin, primidone, rifampicin, and HIV medication ritonavir, nevirapine and efavirenz and possibly also felbamate, griseofulvin, oxcarbazepine, topiramate and products containing the herbal remedy St. John's Wort (hypericum perforatum).

Substances with variable effects on the clearance of contraceptive hormones:
When co-administered with sex hormones, many combinations of HIV protease inhibitors (e.g. ritonavir, nelfinavir) and non-nucleoside reverse transcriptase inhibitors (e.g. nevirapine, efavirenz) and/or combinations with Hepatitis C virus (HCV) medicinal products (e.g. boceprevir, telaprevir), can increase or decrease plasma concentrations of progestins. The net effect of these changes may be clinically relevant in some cases.

Therefore, the prescribing information of concomitant HIV/HCV medications should be consulted to identify potential interactions and any related recommendations. In case of any doubt, an additional barrier contraceptive method should be used by women on protease inhibitor or non-nucleoside reverse transcriptase inhibitor therapy.

Substances decreasing the clearance of contraceptive hormones (enzyme inhibitors):
The clinical relevance of potential interactions with enzyme inhibitors remains unknown. Concomitant administration of strong or moderate CYP3A4 inhibitors such as azole antifungals (e.g. fluconazole, itraconazole, ketoconazole, voriconazole), verapamil, macrolides (e.g. clarithromycin, erythromycin), diltiazem and grapefruit juice can increase plasma concentrations of the progestogen.

In a multiple dose study evaluating the daily (10 days) co-administration of the strong CYP3A4 inhibitor ketoconazole with two drospirenone-containing hormone preparations (drospirenone 3 mg + estradiol 1.5 mg and drospirenone 3 mg + ethinylestradiol 0.02 mg) the AUC (0-24h) of drospirenone was increased 2.3-fold and 2.7-fold, respectively.

Influence of Drospirenone (Slinda) on other medicinal products
Hormonal contraceptives may affect the metabolism of certain other active substances. Accordingly, plasma and tissue concentrations may either increase (e.g. cyclosporine) or decrease (e.g. lamotrigine).

Based on in vitro studies and in vivo interaction studies in female volunteers using omeprazole, simvastatin and midazolam as marker substrate, a clinically relevant interaction of drospirenone with the cytochrome P450 mediated metabolism of other active substances is unlikely.

Pharmacodynamic interactions
Published data did not show a significant effect on serum potassium following the concomitant use of drospirenone and ACE-inhibitors or NSAIDs in patients without renal insufficiency. The concomitant use of Drospirenone (Slinda) with aldosterone antagonists or potassium-sparing diuretics has not been studied. In this case, serum potassium should be tested during the first treatment cycle (see section 4.4).

4.6 Fertility, pregnancy and lactation
Pregnancy
Drospirenone (Slinda) should not be used during pregnancy. If pregnancy occurs during treatment with Drospirenone (Slinda), further intake should be stopped. Epidemiological studies have revealed neither an increased risk of birth defects in children born to women who used drospirenone prior to pregnancy, nor a teratogenic effect when drospirenone was taken inadvertently during pregnancy.

Animal studies have shown reproductive toxicity (see section 5.3) Based on these animal data, undesirable effects due to hormonal action of the active compound cannot be excluded.

Breastfeeding
Negligible amounts of drospirenone are excreted in the breast milk. The daily dose of drospirenone in the baby is <1% of the maternal dose. Thus, at therapeutic doses of Drospirenone (Slinda), no effects on the breastfed newborns/infants are anticipated. Based on the available data, Drospirenone (Slinda) may be used during lactation.

Fertility
Drospirenone (Slinda) is indicated for the prevention of pregnancy.

4.7 Effects on ability to drive and use machines
No studies on the influence on the ability to drive and use machines have been performed with Drospirenone (Slinda). No effects on ability to drive and use machines have been observed in users of oral hormonal contraceptives.

4.8 Undesirable effects
Changes in the bleeding pattern was an adverse reaction frequently reported in the clinical trials (see section 5.1). The most commonly reported adverse reactions in long-term clinical trials of more than 9 cycles of treatment with Drospirenone (Slinda) (2,700 women) were acne (3.8%), metrorrhagia (2.9%), headache (2.7%) and breast pain (2.2%).
Tabulated list of adverse reactions

Adverse reactions that have been reported in short- and long- term clinical trials with Drospirenone (Slinda) are listed in the table below. All adverse reactions are listed by system organ class and frequency: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000).

System Organ Class (MedDRA version 17.1)	Common	Uncommon	Rare
Infections and infestations		Vaginal infection	
Neoplasms benign, malignant and unspecified		Uterine leiomyoma	
Blood and lymphatic system disorders		Anaemia	
Immune system disorders		Hypersensitivity	
Metabolism and nutrition disorders		Appetite disorder Hyperkalaemia	
Psychiatric disorders	Libido disorder Mood disturbances	Anxiety symptoms Depression Depressed mood	
Nervous system disorders	Headache	Dizziness	
Eye disorders			Contact lens intolerance
Vascular disorders		Hot flush Hypertension	
Gastrointestinal disorders	Nausea Abdominal pain	Vomiting Diarrhoea Constipation	
Skin and subcutaneous tissue disorders	Acne	Alopecia Hyperhidrosis Rash,Seborrhoea Pruritus, Dermatitis	

System Organ Class (MedDRA version 17.1)	Common	Uncommon	Rare
Renal and urinary disorders			Polyuria
Reproductive system and breast disorders	Breast discomfort Metrorrhagia Vaginal haemorrhage Dysmenorrhea Menstruation irregular	Amenorrhea Menstrual disorders Pelvic pain Ovarian cyst Vulvovaginal dryness Vaginal discharge	Breast cyst Cervical dysplasia Galactorrohoea Vulvovaginal pruritus
General disorders and administration site conditions		Fatigue Oedema peripheral	
Investigations	Weight increased	Increase in: Transaminases Blood bilirubin Blood creatine phosphokinase Gamma-Glutamyl-transferase Blood triglyceride	Weight decreased

4.9 Overdose
There have been no reports of serious deleterious effects from overdose. Symptoms that may occur in this case are nausea, vomiting and slight vaginal bleeding. There are no antidotes and further treatment should be symptomatic.
Drospirenone however is a spironolactone analogue which has antimineralocorticoid properties. Serum potassium and sodium, and evidence of metabolic acidosis, should be monitored in cases of overdose.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Hormonal contraceptives for systemic use, progestogens
ATC code: G03AC10

Mechanism of action
Drospirenone (Slinda) is a progestogen-only-pill which contains the progestogen drospirenone, derived from spironolactone. In a therapeutic dosage, drospirenone also possesses anti-androgenic and mild anti-mineralocorticoid properties. It has no estrogenic, glucocorticoid and anti-glucocorticoid activity. This gives drospirenone a pharmacological profile closely resembling the natural hormone progesterone.
There are indications from clinical studies that for combined hormonal contraceptives containing 3 mg drospirenone and 0.02 mg ethinylestradiol, the mild anti-mineralocorticoid properties result in a mild anti-mineralocorticoid effect.

Pharmacodynamic effects
The contraceptive effect of Drospirenone (Slinda) is achieved primarily by inhibition of ovulation. Drospirenone exhibits a strong anti-gonadotropic activity inhibiting follicular stimulation and ovulation by suppression of the luteinising hormone (LH). In addition, drospirenone has an effect on the cervix increasing the viscosity of the cervical mucus. Drospirenone also exerts progestational effects on the endometrium, which becomes thinner.

Clinical efficacy and safety
The ovulation inhibition potential of Drospirenone (Slinda) (drospirenone 4 mg non-micronized administered daily for 24 days) as reflected by the ovarian activity [follicular growth, endogenous estradiol and progesterone serum concentrations (Hoogland score)] in comparison to 0.075 mg of desogestrel administered daily for 28 days over two treatment cycles was assessed in a randomized, open-label Phase II study conducted in 60 healthy young women. In cycle 1, no ovulation was observed in either treatment, whereas one ovulation was observed for Drospirenone (Slinda) and one for 0.075 mg of desogestrel group in cycle 2.

In a Phase II study performed in 130 women, Drospirenone (Slinda) maintained the inhibition of ovulation in spite of four fixed scheduled delayed intakes of 24 hours each on day 3, 6, 11 and 22.

In two multicenter Phase III European clinical trials, one single-arm study and one controlled study vs. desogestrel 0.075 mg, 1596 women have been treated for 9 up to 13 consecutive cycles with Drospirenone (Slinda) and 341 with desogestrel for 9 months. In the pooled analysis of these two studies the following Pearl Indexes were calculated:
Pearl Index (18-45 years of age), user + method failure: 0.73 (upper limit 95% confidence interval 1.43)
Pearl Index (18-35 years of age), user + method failure: 0.93 (upper limit 95% confidence interval 1.84)

In a single arm multicenter Phase III clinical trial performed in 39 US sites, the efficacy population consisted of 953 females ≤ 35 years of age with 5,547 evaluable cycles. During these cycles, 17 (1.8 %) pregnancies were reported (irrespectively of confirmation by urine and serum pregnancy tests at the study site) leading to a Pearl Index (95% CI) of 4.0 (2.3, 6.4).

Bleeding pattern
The bleeding pattern during use of Drospirenone (Slinda) was assessed in a 9-month comparative, double blind trial vs desogestrel 0.075 mg, used continuously.
The occurrence of a *withdrawal bleeding* (defined as a bleeding starting during the 4 hormone-free days of Drospirenone (Slinda) lasting for up to 8 consecutive days), was highest – occurring in less than 40% - during the first cycles and decreased with time. After 9 months of use, a withdrawal bleeding was recorded in less than 20% of users.

The mean *number of bleeding/spotting days* in the Drospirenone (Slinda) group vs the desogestrel group during the cycles 2-4 was 13.1 ± 13.0 vs 16.9 ± 16.9, respectively. The mean number of bleeding/spotting days during cycles 7-9, was 9.7 ± 10.4 vs 10.8 ± 13.3, respectively.

In the same study, the proportion of subjects *without any bleeding/spotting (amenorrhea)* during cycles 2-4 was 20.1% for Drospirenone (Slinda) and 13.5% for desogestrel. The proportion of subjects with amenorrhea increased in cycles 7-9 to 26.7% for Drospirenone (Slinda) and to 32.1% in the desogestrel group.

The number of subjects with *prolonged bleeding* (>10 consecutive days) for Drospirenone (Slinda) vs desogestrel was 18.1% and 26.1 %, respectively, during cycles 2-4 and 9.1% and 16.7%, respectively, during cycles 7-9.
The rate of subjects who withdrew from the study due to bleeding related adverse events was 3.3 % in the Drospirenone (Slinda) group and 6.6 % in the desogestrel group.

Paediatric population
A phase III study was conducted in Europe to evaluate tolerability, safety and acceptability of Drospirenone (Slinda). 103 adolescents were included in a 6-cycle core part and 7 additional cycles (extension phase) for a total of 13 cycles, Drospirenone (Slinda) was well tolerated and accepted by the subjects.

Bleeding pattern with Drospirenone (Slinda) was assessed and data were generally consistent with those from the Phase 3 studies in adults. Drospirenone (Slinda) was associated with a decrease in the percentage of subjects experiencing bleeding or spotting over time.

5.2 Pharmacokinetic properties
Absorption
Orally administered drospirenone is rapidly and almost completely absorbed. Maximum concentrations of Drospirenone (Slinda) active substance in plasma of about 28 ng/ml are reached at about 3-4 hours after single ingestion. Concomitant ingestion of food has no influence on the extent of absorption of drospirenone.

The pharmacokinetics of Drospirenone (Slinda) after single and repeated dose has been studied in comparison with the marketed product containing 3 mg of micronized drospirenone in combination with ethinyl estradiol. After multiple dose administration, the relative bioavailability of Drospirenone (Slinda) was 76.51 % for AUCt,ss. The accumulation ratio expressed by Rac (AUC) was 1.9256 while it was 2.7684 for the combined product. These findings indicate that the total exposure to drospirenone is lower for Drospirenone (Slinda) than for the combined product on the market in a cycle of 28 days.

Distribution
Drospirenone is 95 % to 97 % bound to serum albumin and does not bind to sex hormone binding globulin (SHBG) or corticosteroid binding globulin (CBG). The mean apparent volume of distribution of drospirenone is approximately 4 l/kg.

Biotransformation
Drospirenone is extensively metabolized after oral administration. Two major non-pharmacologically active metabolites in the plasma are the acid form of drospirenone, generated by opening of the lactone ring, and the 4,5-dihydro-drospirenone-3-sulfate, both of which are formed without involvement of the P450 system. Drospirenone is also subject to oxidative metabolism catalyzed by CYP3A4.

In vitro, drospirenone is capable to inhibit weakly to moderately the cytochrome P450 enzymes CYP1A1, CYP2C9, CYP2C19 and CYP3A4.

Elimination
After oral administration, plasma drospirenone levels decrease with a terminal half-life of 32 hours. The metabolic clearance rate of drospirenone in serum is 1.5 ± 0.2 ml/min/kg. Drospirenone is excreted only in trace amounts in unchanged form. The metabolites of drospirenone are excreted with the faeces and urine at an excretion ratio of about 1.2 to 1.4.

Linearity/non-linearity
The pharmacokinetics of oral drospirenone is dose proportional following single doses ranging from 1-10mg.

Steady-state conditions
During a treatment cycle, maximum steady-state concentrations of drospirenone in serum of about 40 ng/ml are reached after about 7 days of treatment. Plasma drospirenone levels accumulate by a factor of about 2 as a consequence of the ratio of terminal half-life and dosing interval.

Special populations
Effect of renal impairment
No studies have been conducted to evaluate the effect of renal impairment on the pharmacokinetics of Drospirenone (Slinda). However, steady-state serum drospirenone levels in women under treatment with a COC containing drospirenone with mild renal impairment (creatinine clearance CLcr, 50-80 mL/min) were comparable to those of women with normal renal function. The serum drospirenone levels were on average 37% higher in women with moderate renal impairment (CLcr, 30 - 50 mL/min) compared to those in women with normal renal function. Drospirenone treatment was also well tolerated by women with mild and moderate renal impairment. Drospirenone treatment did not show any clinically significant effect on serum potassium concentration.

Effect of hepatic impairment
No studies have been conducted to evaluate the effect of hepatic disease on the pharmacokinetics of Drospirenone (Slinda). However, steroid hormones may be poorly metabolized in women with impaired liver function.

In a single dose study in women taking a COC containing drospirenone, oral clearance (CL/F) was decreased approximately 50 % in volunteers with moderate hepatic impairment as compared to those with normal liver function. The observed decline in drospirenone clearance in volunteers with moderate hepatic impairment did not translate into any apparent difference in terms of serum potassium concentrations. Even in the presence of diabetes and concomitant treatment with spironolactone (two factors that can predispose a patient to hyperkalemia) an increase in serum potassium concentrations above the upper limit of the normal range was not observed. It can be concluded that drospirenone is well tolerated in patients with mild or moderate hepatic impairment (Child-Pugh B).

Ethnic groups
No clinically relevant differences in the pharmacokinetics of drospirenone between Japanese and Caucasian women have been observed.

5.3 Preclinical safety data
In laboratory animals, the effects of drospirenone were confined to those associated with the recognised pharmacological action. In particular, reproduction toxicity studies revealed embryotoxic and fetotoxic effects in animals which are considered as species specific. At exposures exceeding those in users of drospirenone, effects on sexual differentiation were observed in rat fetuses but not in monkeys.

Environmental risk assessment studies have shown that drospirenone may pose a risk for the aquatic environment as reproductive effects in fish were evident at 0.087 ug/L (the LOEC). (See section 6.6).

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
White active film-coated tablets:
Tablet core: Microcrystalline cellulose, Lactose, Silica, colloidal (E551), Magnesium stearate (E470b)
Tablet coat: Polyvinyl alcohol, Titanium dioxide (E171), Macrogol, Talc (E553b)

Green placebo film-coated tablets:
Tablet core: Lactose monohydrate, Maize starch, Povidone, Silica, colloidal (E551), Magnesium stearate (E470b)
Tablet coat: Hypromellose (E464), Triacetin, Polysorbate 80 (E433), Titanium dioxide (E171) Indigo carmine aluminium lake (E132), Yellow Iron Oxide (E172)

6.2 Incompatibilities
Not applicable

6.3 Shelf life
Please refer to the outer carton.

6.4 Special precautions for storage
Store at temperatures not exceeding 30ºC.

6.5 Nature and contents of container
Transparent PVC-PVDC/Aluminium blister containing 28 film-coated tablets (24 white active film-coated tablets and 4 green placebo film-coated tablets).

In addition to the carton box, a carton case for the blister is enclosed.

6.6 Instructions for use / handling
Keep out of reach of children.
Do not use after expiry date.

Availability
PVC-PVDC/Aluminum Blister Pack containing 28 film-coated tablets (24 white active film-coated tablets and 4 green placebo film-coated tablets).

FDA Reg. No: DR-XY48147

Caution
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

Adverse Drug Reaction
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of any adverse drug reaction.

Date of First Authorization: June 2022
Date of Revision:

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Embil

10 mm 284 mm 304 mm