MEDROXYPROGESTERONE ACETATE

SAYANA PRESS
104 mg / 0.65 mL Suspension for Subcutaneous (SC) Injection

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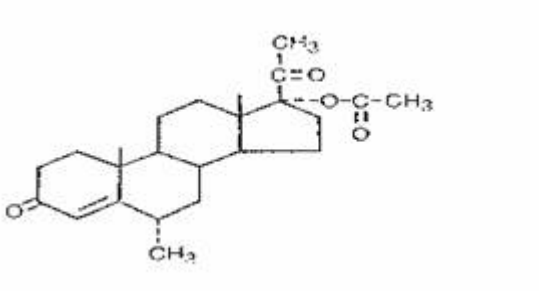
1.0 PHARMACOLOGIC CATEGORY

Hormonal Contraceptive (Progestogen)

2.0 DESCRIPTION

Sayana Press contains medroxyprogesterone acetate (MPA), a derivative of progesterone, as its active ingredient. Medroxyprogesterone acetate is active by the parenteral and oral routes of administration. It is a white to off-white, odorless crystalline powder that is stable in air and that melts between 200°C and 210°C. It is freely soluble in chloroform, soluble in acetone and dioxane, sparingly soluble in alcohol and methanol, slightly soluble in ether, and insoluble in water.

The chemical name for medroxyprogesterone acetate is 17 alpha-acetoxy-6-alpha-methylprogesterone. The structural formula is:



3.0 FORMULATION/COMPOSITION

Medroxyprogesterone acetate (Sayana Press) Suspension for SC Injection: Each 0.65 mL contains 104 mg of medroxyprogesterone acetate (MPA).

4.0 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Depo-Medroxyprogesterone acetate (DMPA) injectable SC suspension (Sayana Press) is indicated for:

Contraception
Contraception

Gynecology
Management of endometriosis-associated pain

4.2 Dosage and Method of Administration

Contraception

DMPA injectable subcutaneous (SC) (Sayana Press) suspension should be vigorously shaken just before use to ensure that the dose being administered represents a uniform suspension.

Subcutaneous (SC)
DMPA SC (Sayana Press) injection must be given by subcutaneous injection into the anterior thigh or abdomen, every 3 months (12-14 weeks). Dosage does not need to be adjusted for body weight, (see **Section 5.2 Pharmacokinetic Properties**). The SC suspension is not formulated for intramuscular injection.

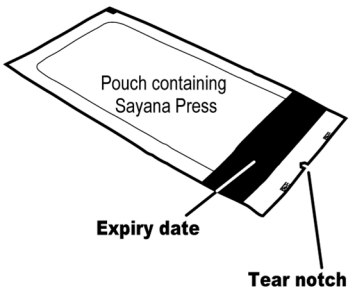
Self-injection

DMPA SC (Sayana Press) 104 mg/0.65 mL pre-filled single dose injector may be administered by a healthcare professional (HCP) or, when considered appropriate by the HCP, self-injected by the patient.

Administration of DMPA SC (Sayana Press) 104 mg/0.65 mL pre-filled single dose injector should be initiated under the supervision of a healthcare professional (HCP). After proper training in injection technique and schedule of administration, patients may self-inject with DMPA SC (Sayana Press) 104 mg/0.65 mL pre-filled single dose injector if their HCP determines that it is appropriate and with medical follow-up as necessary.

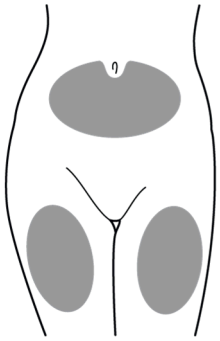
INSTRUCTIONS FOR USE
Preparing and giving an injection with Sayana Press

Introduction
Sayana Press is a disposable injector that contains a single dose of medicine sealed in a reservoir. These instructions show step-by-step how to prepare and give the injection.

Step 1: Getting ready You will need: – A Sayana Press injector (in its sealed foil pouch). – A clean cotton pad or clean paper tissue. • Wash and dry your hands thoroughly before starting. • Check that the pouch does not appear to be damaged. • Check that the expiry date has not passed. • Ensure the pouch is at room temperature.	

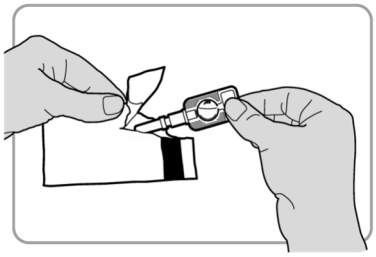
Step 2: Selecting an injection area

- Choose a suitable area for the injection, either the abdomen or the front upper thigh. Avoid bony areas and the navel (belly button).
- The area of skin must be free from scars and skin conditions such as eczema or psoriasis.
- Change the site with each injection.
- Clean the area of skin as your healthcare provider has told you.

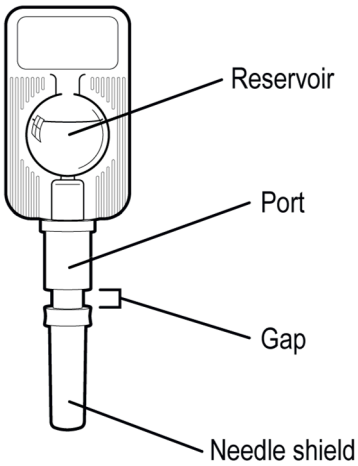


Step 3: Preparing the injector

- Carefully tear open the foil pouch at the tear notch.
- Take out the injector. Do not remove the needle shield from the injector yet.

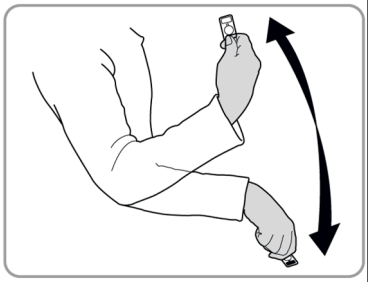


- Check the injector. There should be a gap between the needle shield and the port.
- Discard the injector and use a new one if:
  - There is no gap.
  - The injector is damaged.
  - The needle shield has come off or is missing.

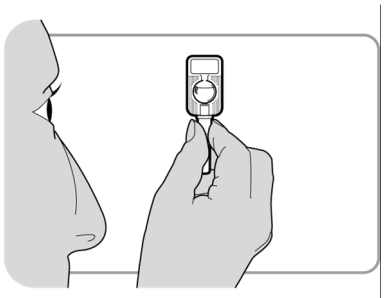


Step 4: Mixing the medicine

- Hold the injector firmly by the port.
- Shake the injector vigorously for at least 30 seconds to mix the medicine.

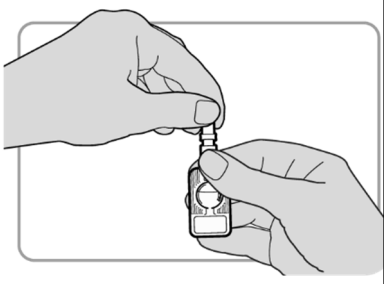


- The medicine should appear white and uniform. If it is not, discard the injector and use a new one.
- If you see liquid leaking out or any other problem, discard the injector and use a new one.
- If there is a delay before injecting, you must repeat the mixing step.

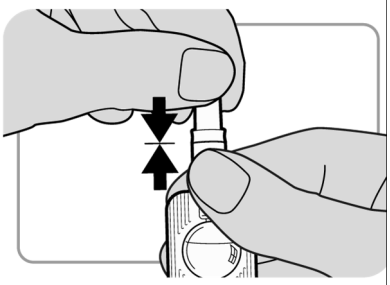


Step 5: Activating the injector

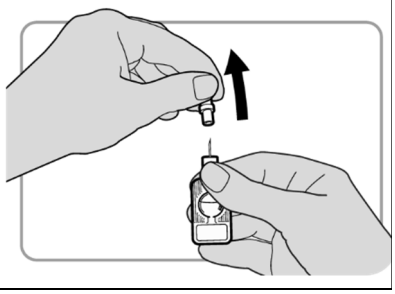
- Hold the injector firmly by the port, making sure the needle shield is pointing upwards. Take care not to squeeze the reservoir.
- Hold the needle shield with the other hand.



- Push the needle shield firmly towards the port until it will go no further. The injector is now activated.

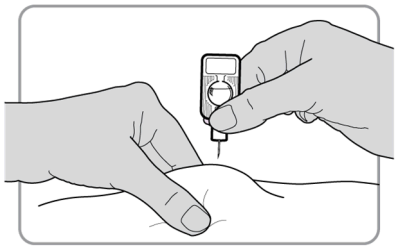


- Pull the needle shield off, and discard it.

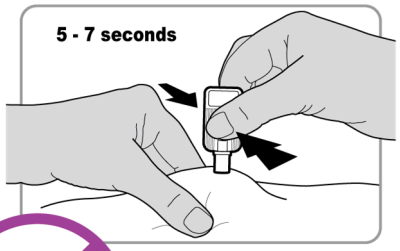


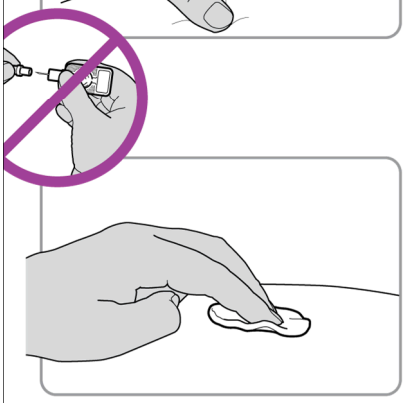
Step 6: Injecting the dose

- Gently pinch a large area of skin. Keep the skin pinched all through this step.
- Hold the injector by the port with the needle pointing straight downwards.
- Insert the needle into the skin so that the port just touches the skin.



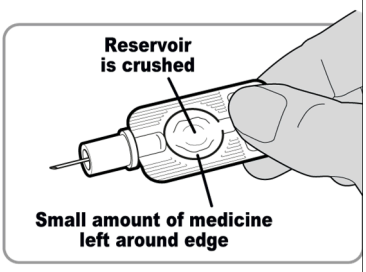
- Squeeze the reservoir slowly to inject the medicine. You should take about **5-7 seconds** to do this.
- Gently pull the needle out of the skin. Let go of the skin.
- Check whether any medicine has leaked out of the injector or has appeared on the skin.
- **Do not replace the needle shield.**
- Use a clean cotton pad to press lightly on the injection area for a few seconds. Do not rub the area.





<u>Important advice</u>

- After the injection a small amount of medicine will be left around the inside edge of the reservoir. This is normal.
- However, if any medicine has leaked out of the injector or appeared on the skin, then a problem may have occurred.
- **If you believe for any reason that the full dose has not been given, speak to your healthcare provider about alternative methods of contraception until the next scheduled injection.**
- **Do not inject an additional dose.**
- **<u>After injection care</u>:**
- If you get any symptoms of allergic reaction (see leaflet Section 4 above) seek medical help immediately.
- Monitor the appearance of the injection site until the next injection. If you notice any skin indentation or dimpling at the injection site, tell your healthcare provider.



Step 7: Disposing of the injector

• The injector should be disposed of as instructed by your healthcare provider. • The injector is for a single injection only and must not be re-used. **Step 8: Record the date of your injection and should you wish to continue, calculate the date of your next scheduled injection of Sayana Press** Retain this leaflet for your records.	Date_____ Date of Next Injection (*add 3 months*) _____

Initial injection
The initial SC injection should be given during the first 5 days after the onset of a normal menstrual period; within 5 days postpartum if not breast feeding; or, if exclusively breast-feeding, at or after 6 weeks postpartum.

Second and subsequent injections
If more than 14 weeks have elapsed since the last SC injection, pregnancy should be ruled out before administering the next SC injection.

Switching from other methods of contraception
When switching from other contraceptive methods, DMPA SC (Sayana Press) should be given in a manner that ensures continuous contraceptive coverage based upon the mechanism of action of both methods, (e.g., patients switching from oral contraceptives should have their first injection of DMPA SC (Sayana Press) within 7 days after taking their last active pill).

Gynecology

Use of combined estrogen / progestin therapy in postmenopausal women should be limited to the lowest effective dose and the shortest duration consistent with treatment goals and risks for the individual woman, and should be periodically evaluated. (see **Section 4.4 – Special Warnings and Precautions for Use**.)

Periodic check-ups are recommended with a frequency and nature adapted to the individual woman. (see **Section 4.4 – Special Warnings and Precautions for Use**.)

Unless there is a previous diagnosis of endometriosis, it is not recommended to add a progestin in a woman without an intact uterus.

Endometriosis
Injectable DMPA (Sayana Press) given subcutaneously 104 mg every 3 months for at least 6 months

Hepatic Insufficiency
No clinical studies have evaluated the effect of hepatic disease on the pharmacokinetics of Medroxyprogesterone acetate (MPA). However, MPA is almost exclusively eliminated

by hepatic metabolism and steroid hormones may be poorly metabolized in patients with severe liver insufficiency, (see **Section 4.3 – Contraindications**).

Renal Insufficiency
No clinical studies have evaluated the effect of renal disease on the pharmacokinetics of MPA. However, since MPA is almost exclusively eliminated by hepatic metabolism, no dosage adjustment should be necessary in women with renal insufficiency.

4.3 Contraindications

MPA is contraindicated in patients with following conditions:

- Known or suspected pregnancy
- Undiagnosed vaginal bleeding
- Severe liver dysfunction
- Known hypersensitivity to MPA (104 mg) or any component of the drug such as Methyl parahydroxybenzoate (1.04 mg), Propyl parahydroxybenzoate (0.0975 mg), Sodium chloride (5.2 mg), Polyethylene glycol (18.688 mg), Polysorbate 80 (1.95 mg), Monobasic sodium phosphate (0.451 mg), Disodium phosphate dodecahydrate (0.382 mg), Methionine (0.975 mg), Povidone (3.25 mg), Sodium hydroxide (qs), Hydrochloric acid (qs).

Additional Contraindication(s) for Specific Use

Contraception / Gynecology: Known or suspected malignancy of the breast

4.4 Special Warnings and Precautions for Use

General

- Unexpected vaginal bleeding during therapy with MPA should be investigated.
- MPA may cause some degree of fluid retention, therefore, caution should be exercised in treating any patient with a pre-existing medical condition that might be adversely affected by fluid retention.
- Patients with a history of treatment for clinical depression should be carefully monitored while receiving MPA therapy.
- Some patients receiving MPA may exhibit a decreased glucose tolerance. Diabetic patients should be carefully observed while receiving such therapy.
- The pathologist (laboratory) should be informed of the patient's use of MPA if endometrial or endocervical tissue is submitted for examination.
- The physician/laboratory should be informed that use of MPA may decrease the levels of the following endocrine biomarkers:
    a. Plasma/urinary steroids (e.g., cortisol, estrogen, pregnanediol, progesterone, testosterone)
    b. Plasma/urinary gonadotrophins (e.g., luteinizing hormone (LH) and follicle-stimulating hormone (FSH))
    c. Sex-hormone-binding-globulin
- Medication should not be readministered pending examination if there is a sudden partial or complete loss of vision or if there is a sudden onset of proptosis, diplopia, or migraine. If examination reveals papilledema or retinal vascular lesions, medication should not be readministered.

- MPA has not been causally associated with the induction of thrombotic or thromboembolic disorders, however MPA is not recommended in any patient with a history of venous thromboembolism (VTE). Discontinuation of MPA is recommended in patients who develop VTE while undergoing therapy with MPA.

Additional Warnings and Precautions for Specific Use or Formulation

Contraception / Endometriosis - Injectable Formulations

BMD Changes in Adult Women after Six Months of Treatment for Endometriosis

In two clinical studies of 573 adult women with endometriosis, the BMD effects of 6 months of DMPA SC (Sayana Press) treatment were compared to 6 months of leuprolide treatment. Subjects were then observed, off therapy, for an additional 12 months.

The proportion of patients with a decrease of 5% or more in BMD was statistically significantly greater in the leuprolide group compared with DMPA SC (Sayana Press) at each time point (Table 1).

Table 1. Proportion of Patients with a Decrease of 5% or More from Baseline after 6 Months on Therapy with DMPA-SC (Sayana Press) or Leuprolide and 6 Months after Stopping Therapy (Studies 268 and 270 Combined)

BMD Parameter	DMPA-SC (Sayana Press) n/N* (%)	Leuprolide n/N* (%)	p-value**
End of Treatment (6 Months of Therapy)			
Spine	12/208 (5.8%)	85/229 (37.1%)	<0.001
Total Hip	1/207 (0.5%)	25/227 (11.0%)	<0.001
At 12 Month Visit (6 Months Off-Therapy)			
Spine	8/166 (4.8%)	32/178 (18.0%)	<0.001
Total Hip	3/166 (1.8%)	25/178 (14.0%)	<0.001

* n=number of patients with a decrease in BMD ≥5%; N=total observations
** chi-square

Other birth control methods or endometrial treatments should be considered in the risk/benefit analysis for the use of DMPA injection (Sayana Press) in women with osteoporotic risk factors such as:

- Chronic alcohol and/or tobacco use
- Chronic use of drugs that can reduce bone mass, e.g., anticonvulsants or corticosteroids
- Low body mass index (BMI) or eating disorder, e.g., anorexia nervosa or bulimia
- Metabolic bone disease
- Strong family history of osteoporosis

It is recommended that all patients have adequate calcium and Vitamin D intake.

Contraception

- Most women using DMPA injectable suspension experience disruption of menstrual bleeding patterns (e.g., irregular or unpredictable bleeding/spotting, rarely, heavy or continuous bleeding). As women continue using DMPA injectable suspension, fewer experience irregular bleeding and more experience amenorrhea.
- Long-term case-controlled surveillance of users of DMPA injectable suspension found slight or no increased overall risk of breast cancer and no overall increased risk of ovarian, liver, or cervical cancer and a prolonged, protective effect of reducing the risk of endometrial cancer.
- There was a tendency for women to gain weight while on therapy with DMPA.
- If jaundice develops, consideration should be given to not readminister the drug.

Sexually Transmitted Infections

Women should be counseled that DMPA injectable suspension does not protect against sexually transmitted infections (STIs) including HIV infection (AIDS) but equally, DMPA is a sterile injection and, used as directed, will not expose them to sexually transmitted infections. Safer sex practices including correct and consistent use of condoms reduce the transmission of STIs through sexual contact, including HIV.

Gynecology-Injectable Formulations

- Prolonged anovulation with amenorrhea and/or erratic menstrual patterns may follow the administration of either a single or multiple injectable dose of DMPA.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Aminoglutethimide administered concomitantly with high doses of oral MPA may significantly depress the serum concentrations of medroxyprogesterone acetate. Users of high-dose oral MPA should be warned of the possibility of decreased efficacy with the use of aminoglutethimide.

Medroxyprogesterone acetate (MPA) is metabolized *in-vitro* primarily by hydroxylation via the CYP3A4. Specific drug-drug interaction studies evaluating the clinical effects with CYP3A4 inducers or inhibitors on MPA have not been conducted and therefore the clinical effects of CYP3A4 inducers or inhibitors are unknown.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

MPA is contraindicated in women who are pregnant.

Some reports suggest under certain circumstances, an association between intrauterine exposure to progestational drugs in the first trimester of pregnancy and genital abnormalities in fetuses.

Infants from unintentional pregnancies that occur 1 to 2 months after injection of DMPA injectable suspension may be at an increased risk of low birth weight, which, in

turn, is associated with an increased risk of neonatal death. The attributable risk is low because pregnancies while on DMPA are uncommon.

If the patient becomes pregnant while using this drug, the patient should be apprised of the potential hazard to the fetus.

Lactation

MPA and its metabolites are excreted in breast milk. There is no evidence to suggest that this presents any hazard to the nursing child**.**

4.7 Effects on Ability to Drive and Use Machines

The effect of medroxyprogesterone acetate on the ability to drive and use machinery has not been systematically evaluated.

4.8 Undesirable Effects

CONTRACEPTION

System Organ Class	**Adverse Drug Reactions**
Immune system disorders	Anaphylactic reaction*, anaphylactoid reaction*, angioedema*, drug hypersensitivity*
Metabolism and nutrition disorders	Fluid retention, increased appetite, decreased appetite
Psychiatric disorders	Depression, insomnia, anxiety, emotional disorder, affective disorder, irritability, anorgasmia, libido decreased
Nervous system disorders	Migraine, dizziness, headache
Ear and labyrinth disorders	Vertigo
Vascular disorders	Hypertension, varicose veins, hot flush
Gastrointestinal disorders	Abdominal pain, nausea, abdominal distension,
Skin and subcutaneous tissue disorders	Alopecia, acne, hirsutism, lipodystrophy acquired*, dermatitis, ecchymosis, chloasma, rash
Musculoskeletal and connective tissue disorders	Back pain, muscle spasms, pain in extremity
Reproductive system and breast disorders	Menometrorrhagia, metrorrhagia, menorrhagia, ovarian cyst, dysmenorrhea, amenorrhea, vaginitis, vaginal discharge, dyspareunia, pelvic pain, vulvovaginal dryness, breast pain, premenstrual syndrome, breast tenderness, breast enlargement
General disorders and administration site conditions	Fatigue, injection-site reaction*, injection site persistent atrophy/indentation/dimpling*, injection site nodule/lump*, injection site pain/tenderness*,
Investigations	Hepatic enzyme abnormal, weight increased, smear cervix abnormal, weight decreased
* ADR identified post-marketing	

GYNECOLOGY - *Endometriosis-Associated Pain*

System Organ Class	**Adverse Drug Reactions**
Immune system disorders	Anaphylactic reaction*, anaphylactoid reaction*, angioedema*, drug hypersensitivity*

Psychiatric disorders	Depression, insomnia, anxiety, affective disorder, irritability, libido decreased
Nervous system disorders	Migraine, dizziness, formication, headache, hypersomnia, paresthesia
Cardiac disorders	Palpitations
Vascular disorders	Hot flush
Gastrointestinal disorders	Nausea, abdominal distension,
Skin and subcutaneous tissue disorders	Alopecia, acne, lipodystrophy acquired*, dermatitis
Musculoskeletal and connective tissue disorders	Arthralgia, pain in extremity
Reproductive system and breast disorders	Dysfunctional uterine bleeding (irregular, increase, decrease, spotting), metrorrhagia, menorrhagia, ovarian cyst, galactorrhea, vaginitis, pelvic pain, vulvovaginal dryness, breast pain, breast tenderness
General disorders and administration site conditions	Fatigue, injection-site reaction*, injection site persistent atrophy/indentation/dimpling*, injection site nodule/lump*, injection site pain/tenderness*[
Investigations	Weight increased, weight decreased
* ADR identified post-marketing	

4.9 Overdose and Treatment

Oral doses up to 3 g per day have been well tolerated. Overdose treatment is symptomatic and supportive.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Medroxyprogesterone acetate (17a-hydroxy-6a-methylprogesterone acetate) is a derivative of progesterone.

Mechanism of Action

MPA is a synthetic progestin (structurally related to the endogenous hormone progesterone) which has been demonstrated to possess several pharmacologic actions on the endocrine system:

- Inhibition of pituitary gonadotropins (FSH and LH);
- Decrease of ACTH and hydrocortisone blood levels;
- Decrease of circulating testosterone;
- Decrease of circulating estrogen levels (as the result of both FSH inhibition and enzymatic induction of hepatic reductase, resulting in increased clearance of testosterone and consequent decreased conversion of androgens to estrogens).

All of these actions result in a number of pharmacological effects as described below.

Contraception
DMPA, when administered parenterally at the recommended dose to women, inhibits the secretion of gonadotropins which, in turn, prevents follicular maturation and ovulation and causes thickening of cervical mucus which inhibits sperm entry into the uterus.

Gynecology
Medroxyprogesterone acetate (MPA), administered orally or parenterally in the recommended doses to women with adequate endogenous estrogen, transforms proliferative into secretory endometrium. Androgenic and anabolic effects have been noted, but the drug is apparently devoid of significant estrogenic activity. While parenterally administered DMPA inhibits gonadotropin production, which in turn prevents follicular maturation and ovulation, available data indicate that this does not occur when the usually recommended oral dosage is given as single daily doses.

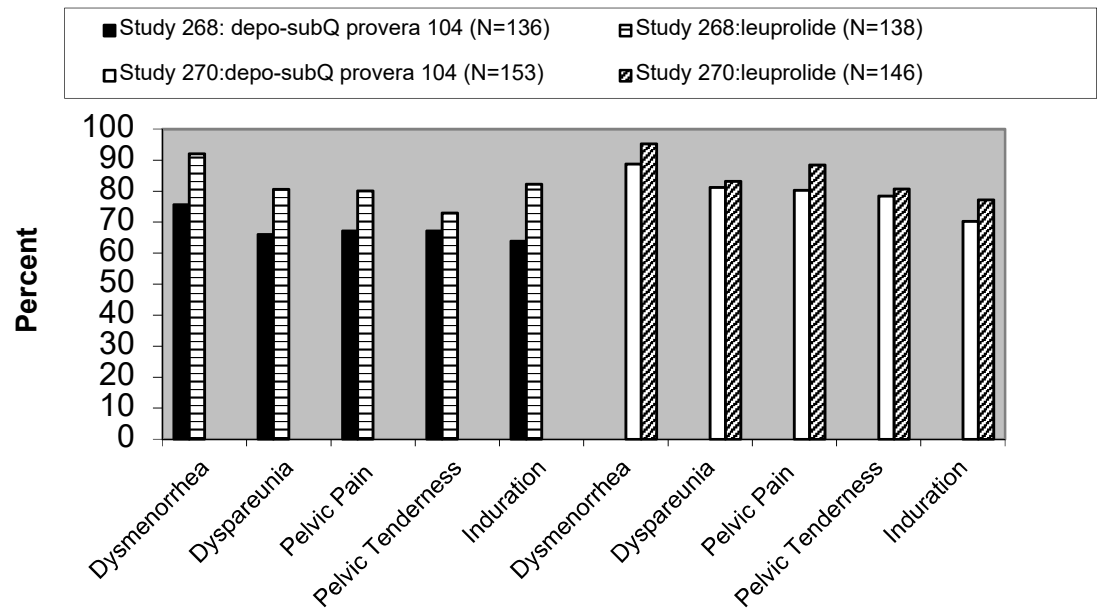
Endometriosis
Suppression of serum estradiol concentrations and a possible direct action of DMPA-SC (Sayana Press) on the lesions of endometriosis are likely to be responsible for the therapeutic effect on endometriosis-associated pain.

Endometriosis Studies

The efficacy of DMPA-SC (Sayana Press) in the reduction of endometriosis-associated pain in women with the signs and symptoms of endometriosis was demonstrated in two active comparator-controlled studies. Each study assessed reduction in endometriosis-associated pain over 6 months of treatment and recurrence of symptoms for 12-months post treatment. Subjects treated with DMPA-SC (Sayana Press) for 6 months received a 104 mg dose every 3 months (2 injections), while women treated with leuprolide microspheres for 6 months received a dose of 11.25 mg every 3 months (2 injections) or 3.75 mg every month (6 injections). Study 268 was conducted in the USA and Canada and enrolled 274 subjects (136 on DMPA-SC (Sayana Press) and 138 on leuprolide). Study 270 was conducted in South America, Europe and Asia, and enrolled 299 subjects (153 on DMPA-SC (Sayana Press) and 146 on leuprolide).

Reduction in pain was evaluated using a modified Biberoglu and Behrman scale that consisted of three patient-reported symptoms (dysmenorrhea, dyspareunia, and pelvic pain not related to menses) and two signs assessed during pelvic examination (pelvic tenderness and induration). For each category, a favorable response was defined as improvement of at least 1 unit (severity was assessed on a scale of 0 to 3) relative to baseline score (Figure 1).

Figure 1. Percentages of Responders at End of Treatment (Month 6 or Last Assessment if Earlier) in Studies 268 & 270



Favorable Response = reduction in severity of symptom or sign of ≥ 1 point on a scale of 0 to 3, as compared to baseline

Additionally, scores from each of the five categories were combined, with the total (composite score) considered a global measurement of overall disease improvement. For subjects with baseline scores for each of the 5 categories, a mean decrease of 4 points relative to baseline was considered a clinically meaningful improvement. Across both studies, for both treatment groups, the mean changes in the composite score met the protocol-defined criterion for improvement.

In the clinical trials, treatment with DMPA-SC (Sayana Press) was limited to six months. Data on the persistence of benefit with longer treatment are not available.

Subjects recorded daily the occurrence and severity of hot flushes. Of the DMPA-SC (Sayana Press) users, 28.6% reported experiencing moderate or severe hot flushes at baseline, 36.2% at Month 3, and 26.7% at month 6. Of the leuprolide users, 32.8% reported experiencing moderate or severe hot flushes at baseline, 74.2% at Month 3, and 68.5% at Month 6.

5.2 Pharmacokinetic Properties

Absorption: MPA absorption from the SC injection site to achieve therapeutic levels is relatively prompt. The mean T_{max} attained approximately one week after injection. The peak MPA concentrations (C_{max}) generally range from 0.5 to 3.0 ng/mL with a mean C_{max} of 1.5 ng/mL after a single SC injection.

Effect of Injection Site: DMPA subcutaneous was administered into the anterior thigh or the abdomen to evaluate effects on MPA concentration-time profile. MPA trough

concentrations (C_{min}; Day 91) were similar for the two injection locations, suggesting that injection site does not negatively affect the contraceptive efficacy.

Distribution: Plasma protein binding of MPA averages 86%. MPA binding occurs primarily to serum albumin; no binding of MPA occurs with SHBG (Sex Hormone Binding Globulin).

Metabolism: MPA is extensively metabolized in the liver.

Elimination: Residual MPA concentrations at the end of the dosing interval (3 months) of DMPA subcutaneous are generally below 0.5 ng/mL, consistent with its apparent terminal half-life of ~40 days after SC administration. Most MPA metabolites are excreted in the urine as glucuronide conjugates with only small amounts excreted as sulfates.

Special populations:

Race
There were no apparent differences in the pharmacokinetics and/or dynamics of MPA after SC administration of DMPA subcutaneous among women of all ethnic backgrounds studied. The pharmacokinetics/dynamics of DMPA has been evaluated in Asian women in a separate study.

Effect of Body Weight
No dosage adjustment of DMPA subcutaneous is necessary based on body weight. The effect of body weight on the pharmacokinetics of MPA was assessed in a subset of women (n = 42, body mass index [BMI] ranged from 18.2 to 46.0 kg/m^2). The AUC_{0-91} values for MPA were 68.5, 74.8, and 61.8 ng day/mL in women with BMI categories of ≤ 25 Kg/m^2, >25 Kg/m^2 to ≤30 Kg/m^2, and >30 Kg/m^2, respectively. The mean MPA C_{max} was 1.65 ng/mL in women with BMI ≤ 25 kg/m^2, 1.76 ng/mL in women with BMI >25 Kg/m^2 to ≤30 kg/m^2, and 1.40 ng/mL in women with BMI > 30 kg/m^2, respectively. The range of MPA trough (C_{min}) concentrations and the half-lives were comparable for the 3 BMI groups.

5.3 Preclinical Safety Data

Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term intramuscular administration of medroxyprogesterone acetate (DMPA) has been shown to produce mammary tumors in beagle dogs. There was no evidence of a carcinogenic effect associated with the oral administration of oral MPA to rats and mice. Medroxyprogesterone acetate was not mutagenic in a battery of *in vitro* or *in vivo* genetic toxicity assays. Medroxyprogesterone acetate at high doses is an antifertility drug and high doses would be expected to impair fertility until the cessation of treatment.

6.0 PHARMACEUTICAL PARTICULARS

6.1 Shelf Life

36 months

Please see outer package for the expiry date.

6.2 Special Precautions for Storage

Store at temperatures not exceeding 30°C. Do not refrigerate or freeze.
To be used immediately after opening the foil pouch.

6.3 Availability

Medroxyprogesterone acetate (Sayana Press) 104 mg/0.65 mL Suspension for Subcutaneous Injection is a white to off-white suspension presented in a prefilled single use injection system wrapped in a foil laminate pouch.

7.0 FDA REGISTRATION NUMBER

104 mg / 0.65 mL Suspension for Subcutaneous (SC) Injection: DR-XY47081

8.0 DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

104 mg / 0.65 mL Suspension for Subcutaneous (SC) Injection: 14 January 2021

Keep out of reach of children

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.

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

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