FOLIC ACID

PREVENA
5 mg CAPSULE

℞ VITAMIN

FORMULATION:
Each Capsule contains:
Folic Acid (Vitamin B9) ..... 5 mg

DESCRIPTION:
PREVENA contains 5mg of the active ingredient, folic acid. Folic acid is a member of the vitamin B complex that is needed for healthy red blood cells.
PREVENA is a yellowish or orange crystalline powder. Practically insoluble in water and in most organic solvents. With a molecular weight of 145 mg. In addition to the active ingredient, Folic Acid, Each Capsule contains the following ingredients : magnesium Stearate and Lactose in a Gray (body) and Green (Cap). 10 strips of 10's.(Box of 100's)

WHAT IS IN THE MEDICINE?
A yellow, yellow-brownish, or yellowishorange, odourless crystalline powder. Very slightly solublein water; insoluble in alcohol, in acetone, in chloroform, and in ether.
Each Capsule contains 5mg of the active ingredient, folic acid. Folic acid is a member of the vitamin B complex that is needed for healthy red blood cells. The capsules are used to treat certain types of anaemia caused by faulty development of red blood cells such as after stomach surgery or during pregnancy. They can also be used to prevent the long term breakdown of red blood cells (in certain conditions) or in kidney dialysis.

STRENGTH OF MEDICINE
See Formulation

WHAT IS THIS MEDICINE USED FOR?
For the treatment and prevention of folate deficiencies state. It also used in the women of child-bearing potential and pregnant women to protect against neural tube defects and orofacial clefs in the fetus, in their offspring. Also indicated for chronic hemolytic anemia, exfoliative skin disease, gingivitis, anorectic cancer, cervical dysplasia, elderly patients, gout and cardiovascular disease. They can also be used to prevent the long term breakdown of red blood cells (in certain conditions) or in kidney dialysis.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Folate Dificient Megaloblastic Anemia:
5 mg daily for 4 months up to 15 mg daily in malaboorption states.
Prophylaxis of Megaloblastic in Pregnancy:
0.5 mg up to 1 mg daily.
Prevention of Neural Tube Defects:
4 mg to 5 mg daily starting before pregnancy and continue through the first trimester.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
You must not take folic acid and should talk to your doctor immediately:
- If you have been told you suffer from Vitamin B12 deficiency including pernicious anaemia, or any other blood disorder.
- If you are sensitive/allergic to folic acid or any other ingredients in these tablets.
- If you are suffering from cancer.
- If you have Addison's disease and low vitamin B12 levels in your body.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?
Folic Acid should not be given alone or conjunction with inadequate amounts of Vitamins B_{12} for the treatment of undiagnosed megablastic anemia. It may also produce Haematopoietic response in patients with a megablastic anemia due to Vitamin B_{12} deficiency without preventing aggravation of neurological symptoms. The true deficiency state can lead to serious neurological damage, such as Subacute combined Degeneration of Spinal Cord.

UNDESIRABLE EFFECT OF THIS MEDICINE:
Folic Acid is generally well tolerated. Gastrointestinal disturbance and hypersensitivity reactions have been reported rarely.
PREGNANCY RISK CATEGORY:
Neural tube defects – Failure of the fetal neural tube to fuse normally during the first 4 weeks of pregnancy maybe result in one of several congenital defects. These include anencephaly (absence of the brain and cranial vault) and spina bifida (failure of vertebrae to fuse).

PHARMACOKINETICS:
Folic Acid is rapidly absorbed from the gastrointestinal tract, mainly from the duodenum and jejunum. Dietary folates are stated to have about half the bioavailability of crystalline folic acid. The naturally occuring folate polyglutamates are largely deconjugated and reduced by dihydrofolate reductase in the intestines to form 5-methyltetrahydrofolate, which appears in the portal circulation, where it is extensively bound to plasma proteins, Folic Acid administered therapeutically enters the portal circulation largely unchanged since it is a poor substrate for reduction by dihydrofolate reductase. It is converted to the metabolically active form 5-methyltetrahydrofolate in the plasma and liver. The principal storage of the folate is the liver, it is also actively concentrated in the cerebrospinal fluid. Folate undergoes enterohepatic circulation. Folate metabolites are eliminated in the urine and folate in excess of body requirements is excreted unchanged in the urinc. Folate is distributed into breast milk. Folic Acid is removed by haemodialysis.

WHAT OTHER MEDINES OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
Folate deficiency states may be produced by a number of drugs such as antiepileptics, oral contraceptives, antituberculous drugs, alcohol, and folic acid antagonists such as aminopterin, methotrexate, pyrimethamine, trimethoprim and sulfonamides.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you miss a dose, just take the next dose and subsequent doses at the usual recommended schedule. Do not double dose.

SIGNS AND SYMPTOMS OF OVERDOSE:
*Mothers that take excessive amounts of folic acid during pregnancy may predispose their daughters to diabetes and obesity
*(hypersensitivity) e.g. itchy/ red skin, rash, swelling of the face, lips, tongueor throat or difficulty breathing or swallowing, shock (cold sweaty skin, weak pulse, dry mouth, dilated pupils).
•Stomach and intestines: loss of appetite, feeling sick, a bloated feeling, wind.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?
If you have taken more than the recommended dosage, consult a doctor or contact a Poison Centro Center right away.

HOW SHOULD YOU KEEP THIS MEDICINE?
Store at temperatures not exceeding 30°C.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
Tell your doctor if you notice any of the following side effects:
- Severe allergic reaction (anaphylactic reaction)
- Allergic reaction (hypersensitivity) e.g. itchy/ red skin, rash, swelling of the face, lips, tongue or throat or difficulty breathing or swallowing, shock (cold sweaty skin, weak pulse, dry mouth, dilated pupils).
- Stomach and intestines: loss of appetite, feeling sick, a bloated feeling, wind.

If you have side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

ADR REPORTING STATEMENT:
For suspected adverse drug reaction, report to FDA: www.fda.gov.ph
Patient must seek medical attention immediately at the first sign of any adverse drug reactions.

AVAILABILITY:
PREVENA 5 mg Capsule Alu/Red PVC Blister Pack of 10's (box of 100's)

SHELF-LIFE : 24 Months
Registration No. DR-XY44826

DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION:
01 December 2020

DATE OF REVISION OF PATIENT INFORMATION LEAFLET:
28 October 2020

Manufactured by:
SAN MARINO *Laboratories* CORP.
#1 Crisanto delos Reyes Street
Brgy. Javalera, Gen. Trias, Cavite