SCHEDULING STATUS: S1
PROPRIETARY NAME AND DOSAGE FORM:

GULF FOLIC ACID 5 (tablets)

COMPOSITION:
Each tablet contains 5 mg Folic Acid
Inactive ingredients: Dibasic calcium phosphate, microcrystalline cellulose, magnesium stearate

SUGAR FREE

PHARMACOLOGICAL CLASSIFICATION:
A 22.2 Vitamins, other

PHARMACOLOGICAL ACTION:
Folic acid is rapidly absorbed from the gastrointestinal tract. Folic acid given therapeutically enters the portal circulation largely unchanged. It is converted to the metabolically active form 5-methyltetrahydrofolate in the plasma and liver. The principal storage site of folate is the liver; it is also actively concentrated in the CSF. Folate undergoes enterohepatic circulation. Folate metabolites are eliminated in the urine and folate is excreted unchanged in the urine.
Vitamin supplement

INDICATIONS:
Gulf Folic Acid 5 is indicated for the prophylaxis and treatment of folic acid deficiencies.

CONTRAINDICATIONS:
Hypersensitivity to any of the ingredients
Gulf Folic Acid 5 should never be given alone or in conjunction with inadequate amounts of Vitamin B_{12} for the treatment of megaloblastic or pernicious anaemia.

WARNINGS AND SPECIAL PRECAUTIONS:
Caution is advised in patients who may have folate dependent tumours.

SPECIAL PRECAUTIONS:
Gulf Folic Acid 5 should never be given alone or with inadequate amounts of Vitamin B_{12} for the treatment of undiagnosed megaloblastic anaemia, since folic acid may produce a haematopoietic response in patients with megaloblastic anaemia due to Vitamin B_{12} deficiency without preventing aggravation of neurological symptoms. This masking of the true deficiency state can lead to serious neurological damage, such as sub-acute combined degeneration of the spinal cord (see "Contraindications").

INTERACTIONS:
Folate supplementation has reportedly decreased serum phenytoin concentrations and there is possibility that such an effect could also occur with barbiturate anti-epileptics.
Gulf Folic Acid 5 should not be used with a folic acid antagonist such as methotrexate as this may nullify the effect of the antagonist. Gulf Folic Acid 5 enhances the toxicity, as well as the anti-neoplastic action of fluorouracil, especially on the gastro-intestinal tract.

PREGNANCY AND LACTATION:
Gulf Folic Acid 5 is safe for use in pregnancy and lactation, provided it is used within the prescribed dose for pregnancy (See "Dosage and Directions for use").

DOSAGE AND DIRECTIONS FOR USE:
In the treatment of folic acid deficiency, Gulf Folic Acid 5 may be given by mouth in an initial dose of 10 to 20 mg daily for 14 days; the maintenance dose is 2,5 to 10 mg. In the prophylaxis of megaloblastic anaemia of pregnancy the usual dose is 5 mg daily.

SIDE EFFECTS:
Gastrointestinal disturbances and hypersensitivity reactions including anaphylactic reactions have been reported.

KNOWN SYMPTOMS OF OVER-DOSAGE AND PARTICULARS OF ITS TREATMENT:
Large and continuous doses of Gulf Folic Acid 5 may lower the blood concentration of Vitamin B_{12}. Larger amounts of folate are rapidly excreted in the urine.

IDENTIFICATION:
A yellowish flat tablet with a score-mark on one side and plain on the other side

PRESENTATION:
White polypropylene container and cap of 100, 250 or 1000 tablets.
Patient ready packets of 28 tablets.

STORAGE INSTRUCTIONS:
Store at or below 25 ºC. Protect from light and moisture. Keep container well closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
A40/22.2/0592

NAME AND BUSINESS ADDRESS OF HOLDER OF THE CERTIFICATE OF REGISTRATION:
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