

ROYCE®

# FOLIC ACID TABLET 5MG

(Folic Acid-Vitamin)

**Presentation:**

A yellow, round flat beveled edge, plain tablet with single break line on one side.

Each tablet contains: Folic Acid 5mg.

**Pharmacological Information:**

Folic acid is a member of the vitamin B group. Folic acid is reduced in the body to tetrahydrofolate, which is a coenzyme for various metabolic processes including the synthesis of purine and pyrimidine nucleotides, and hence in the synthesis of DNA; it is also involved in some amino-acid conversion and in the formation and utilisation of formate.

Folic acid is absorbed mainly from the proximal part of the small intestine. The naturally occurring folate polyglutamates are largely deconjugated and reduced prior to absorption. It is the 5-methyltetrahydrofolate which appears in the portal circulation, where it is extensively bound to plasma proteins.

Folic acid is rapidly absorbed from normal diets and is distributed in body tissues. The principal storage site is the liver; it is also actively concentrated in the cerebrospinal fluid. There is an enterohepatic circulation for folate; about 4 to 5 µg is excreted in the urine daily. Administration of larger doses of folic acid leads to proportionately more of the vitamin being excreted in the urine. Folate is distributed into breast milk.

**Indication:**

For the treatment and prevention of folic acid deficiency states, due to megaloblastic anaemia, develops when the dietary intake is inadequate, as in malnutrition, malabsorption, increased utilization as in pregnancy or conditions such as haemolytic anaemia.

**Dosage and Administration:**

For oral use only.

Adult: Megaloblastic anaemia: 5mg daily for 4 months, up to 15mg daily may be necessary in malabsorption states.

Chronic haemolytic: Prophylactic administration 5mg daily or weekly may be necessary in chronic haemolytic states such as thalassaemia major or sickle-cell anaemia, depending on the diet and rate of haemolysis; similar doses may be necessary in some patients receiving renal dialysis in order to prevent deficiency.

**Contraindication:**

Pernicious anaemia.

**Warning and Precautions:**

Folic acid should never be given alone or in conjunction with inadequate amounts of vitamin B12 for the treatment of undiagnosed megaloblastic anaemia. Although folic acid may produce a haematopoietic response in patients with a megaloblastic anaemia due to vitamin B12 deficiency it should not be given alone in vitamin-B12 deficiency states as it may precipitate the onset of subacute combined degeneration of the cord. Therefore, the inclusion of folic acid in multivitamin preparations may be dangerous as an improvement in vitamin B12-dependent megaloblastic anaemia may mask the true deficiency state. Caution is advised in patients who may have folate-dependent tumours.

**Interactions with Other Medicaments:**

Folate status may be affected by a number of drugs and anticonvulsants, oral contraceptives, antituberculous drugs, alcohol, and folic acid antagonists including aminopterin, methotrexate, pyrimethamine, trimethoprim, and sulphonamides have produce folate deficiency states.

**Side Effects:**

Folic acid is usually well tolerated, but anorexia, nausea, abdominal distention and flatulence have been reported.

**Storage Condition:**

Store in a dry place (below 30°C). Protect from light.

**Pack Size:**

Blister pack of 50 x 21's and 110 x 63's.

**Product Registration Number:**

MAL19910328XZ

Further information can be obtained from your doctor or pharmacist.

**Product Holder / Manufactured by:**

**ROYCE PHARMA MFG. SDN.BHD. (650435-X)**

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