

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Folic Acid 5mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Folic Acid BP 5.00 mg.

3. PHARMACEUTICAL FORM

Tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the treatment and prophylaxis of megaloblastic anaemia or pernicious anaemia administered with adequate amounts of hydroxocobalamin.
For the treatment of folic acid deficiency e.g. caused by administration of phenytoin.

4.2. Posology and method of administration

For the treatment of anaemias:

Adults: 5mg daily for up to 4 months, with adequate amounts of hydroxocobalamin by injection. Up to 15mg daily in malabsorption states.

For prophylaxis in haemolytic states or in renal dialysis, adults 5mg daily or even weekly.

This strength tablet is not recommended for children or in pregnancy.

There is no evidence that the dose for the elderly differs.

For oral administration.

4.3 Contraindications

- Known hypersensitivity to the active ingredient or any of the excipients.
- Long -term folate therapy is contraindicated in any patient with untreated cobalamin deficiency. This can be untreated pernicious anaemia or other cause of cobalamin deficiency, including lifelong vegetarians. In elderly people, a cobalamin absorption test should be done before long-term folate therapy. Folate given to such patients for 3 months or longer has precipitated cobalamin neuropathy. No harm results from short courses of folate
- Should not be given alone in Addisons or other Vitamin B12 deficiency states because it may precipitate the onset of subacute combined degeneration of the spinal cord
- Do not use in malignant disease unless megaloblastic anaemia due to folate deficiency is an important complication.

4.4 Special warnings and precautions for use

Caution should be exercised when administering folic acid to patients who may have folate dependent tumours.

4.5 Interaction with other medicinal products and other forms of interaction

- Antiepileptics – Folic Acid possibly reduces plasma concentration of Phenobarbital, phenytoin and primidone. If folic acid supplements are given to treat folate deficiency, caused by these antiepileptics, the serum antiepileptic levels may fall, leading to decreased seizure control in some patients.
- Antibacterials – chloramphenicol and co-trimoxazole may interfere with folate metabolism.
- Sulfasalazine - can reduce the absorption of folic acid.

- Folic acid may interfere with the toxic and therapeutic effects of Methotrexate.

4.6 Pregnancy and lactation

Pregnancy

There are no known hazards to the use of folic acid in pregnancy, supplements of folic acid are often beneficial.

Non-drug induced folic acid deficiency, or abnormal folate metabolism, is related to the occurrence of birth defects and some neural tube defects. Interference with folic acid metabolism or folate deficiency induced by drugs such as anticonvulsants and some antineoplastics early in pregnancy results in congenital anomalies. Lack of the vitamin or its metabolites may also be responsible for some cases of spontaneous abortion and intrauterine growth retardation.

Lactation:

Folic acid is actively excreted in human breast milk. Accumulation of folate in milk takes precedence over maternal folate needs. Levels of folic acid are relatively low in colostrum but as lactation proceeds, concentrations of the vitamins rise. No adverse effects have been observed in breast fed infants whose mothers were receiving folic acid.

4.7. Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

4.9.	Gastrointestinal disorders Rare ($\geq 1/10,000$ to $< 1/1,000$)	Anorexia, nausea, abdominal distension and flatulence
Over dose	Immune system disorders Rare ($\geq 1/10,000$ to $< 1/1,000$)	Allergic reactions, comprising erythema, rash, pruritus, urticaria, dyspnoea, and anaphylactic reactions (including shock).

N
0

data available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code BO3B B01

Folic acid is a member of Vitamin B group. It is used in the treatment and prevention of folate deficiency states.

5.2. Pharmacokinetic properties

Folic acid is absorbed mainly from the proximal part of the small intestine. Folate polyglutamates are considered to be deconjugated to monoglutamates during absorption. Folic acid rapidly appears in the blood where it is extensively bound to plasma protein.

When large amounts are absorbed a high proportion is metabolised in the liver to other active forms of folate and a proportion is stored as reduced and methylated folate. Large amounts of folate are excreted in the urine.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Calcium hydrogen phosphate
Starch
Sodium lauryl sulphate
Magnesium stearate.

6.2. Incompatibilities

None stated.

6.3 Shelf life

3 years for Securitainer

3 years for Blister pack

6.4. Special precautions for storage

Store in a cool dry place protected from light below 25°C.

PRODUCT NAME: FOLIC ACID TABLET 5MG

6.5 Nature and contents of container

Securitainers containing 50, 100, 250, 1000 or 5000 tablets

Blister packs containing 28 tablets

6.6. Instruction for Use and Handling

Not applicable.

Administrative Details

7. MARKETING AUTHORISATION HOLDER

Forley Generics Ltd
NLA tower
12-16 Addiscombe Road
Croydon
CR0 0XT
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 16201/0011

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

22 July 1999

10 DATE OF REVISION OF THE TEXT

05/10/2010