

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Folic Acid Tablets BP 5 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg of Folic Acid Ph. Eur.

3 PHARMACEUTICAL FORM

Tablet.
Yellow, circular compressed tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of megaloblastic anaemia associated with folic acid deficiency.

To reduce the risk of recurrence of neural tube defect (NTD) in women who have already had a baby affected by NTD.

4.2 Posology and method of administration

Folic Acid Tablets BP are for oral administration.

Megaloblastic Anaemia associated with folic acid deficiency.

Adults:

Initial dose: 5 to 20mg daily.

Maintenance: 2.5 to 10 mg daily.

Children:

Aged up to 1 year may be given a maintenance dose of 250 micrograms per kg body-weight daily; 1 to 5 years 2.5 mg daily; 6 to 12 years 5 mg daily. An initial dosage of twice the maintenance dose may be given for 2 days.

To reduce risk of recurrence of NTD. Women who have already had a baby affected by NTD and who may become pregnant again should take one 5 mg tablet daily, commencing before conception and continuing until the twelfth week of pregnancy.

4.3 Contraindications

Use in patients with a known hypersensitivity to folic acid.

4.4 Special warnings and precautions for use

In the treatment of pernicious anaemia, folic acid should never be given alone or in conjunction with in adequate amounts of Vitamin B₁₂ (cyanocobalamin or hydroxocobalamin). Before treatment a megaloblastic anaemia with folic acid, the diagnosis must be fully established and other possible causes outruled.

4.5 Interaction with other medicinal products and other forms of interaction

Folic acid therapy may increase phenytoin metabolism in folate deficient patients, resulting in decreased serum phenytoin concentrations. An increase in seizure frequency may occur in some patients. Large and continuous doses of folic acid lower the plasma concentration of Vitamin B₁₂.

4.6 Pregnancy and lactation

There have been no specific studies in animal reproduction. Studies during human pregnancy have been generally related to deficiencies of folic acid. There is no evidence to indicate that use of folic acid should be avoided during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Nil.

4.8 Undesirable effects

Folic acid is generally well tolerated. Gastrointestinal disturbances may occur. Hypersensitivity reactions such as erythema, itching, general malaise, bronchospasm and fever have been reported.

4.9 Overdose

Overdosages of water-soluble vitamins are unlikely to cause toxicity as they are readily excreted in urine. No emergency procedure or antidote is applicable and any symptoms may be expected to resolve rapidly following withdrawal of the preparation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Folic acid is a member of the Vitamin B group. Following absorption, folic acid is reduced to tetrahydrofolic acid, which is a co-enzyme for various metabolic processes including the biosynthesis of purines and thymidylates of nucleic acids.

5.2 Pharmacokinetic properties

Folic acid is absorbed mainly from the proximal portion of the small intestine. It is reduced and methylated to methyltetrahydrofolic acid which is rapidly transported to tissues. The liver is the main storage site and there is enterohepatic circulation of folate. Administration of large doses of folic acid leads to proportionately more of the vitamin being excreted in urine.

5.3 Preclinical safety data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch

Povidone
Magnesium stearate
Colloidal anhydrous silica

6.2 Incompatibilities

None known.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original container in order to protect from light.

6.5 Nature and contents of container

Polypropylene securitainers with tamper evident polypropylene caps.

Pack sizes: 100, 500, 1000.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Antigen Pharmaceuticals Ltd.
Roscrea
Co. Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 0073/057/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1980

Date of last renewal: 01 April 2000