

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Folic acid 2.5mg/5ml Sugar Free Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of oral solution contains 2.5mg folic acid.

Excipients with known effect

Each 5ml of oral solution contains 9mg of methyl parahydroxybenzoate (E218).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution

A clear yellow colour solution with strawberry odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

1. Folate deficient megaloblastic anaemia
2. Folate deficient megaloblastic anaemia in infants
3. Malabsorption syndromes
 - 3.1 Tropical sprue

- 3.2 Coeliac disease
- 3.3 Non-tropical sprue
- 4. Megaloblastic anaemia in pregnancy
- 5. Megaloblastic anaemia associated with alcoholism
- 6. Megaloblastic anaemia associated with anti-convulsant therapy
- 7. Haemolytic anaemias e.g. sickle cell anaemia

4.2 Posology and method of administration

Posology

Children:

May be given 5mg to 15mg daily, in divided doses, according to the severity of the deficiency state.

Adults:

Initial dose of 10mg to 20mg daily, in divided doses, for 14 days or until a haematopoietic response has been obtained.

Maintenance dose is 2.5mg to 10mg daily.

Prophylactic dose in pregnancy 0.5mg (1ml) daily.

Elderly:

As for adults.

Method of administration

For oral administration only.

4.3 Contraindications

Known hypersensitivity to folic acid.

Known hypersensitivity to hydroxybenzoate esters.

Patients with folate dependent tumours.

Patients with malignant disease, unless megaloblastic anaemia due to folic acid deficiency.

4.4 Special warnings and precautions for use

If folic acid is used indiscriminately, there is a danger that patients with pernicious anaemia and other B₁₂ deficiency states, despite a haematological remission, may develop irreparable neurological lesions. Therefore a full clinical diagnosis should be made before initiating treatment.

Folic acid is removed by haemodialysis.

Excipient warnings

This product contains methyl parahydroxybenzoate (E218), which may cause allergic reactions (possibly delayed).

This product also contains glycerol (E422) which may cause headache, stomach upset and diarrhoea.

4.5 Interaction with other medicinal products and other forms of interaction

Antiepileptics – if folic acid supplements are given to treat folate deficiency, which can be caused by the use of antiepileptics (phenytoin, phenobarbital and primidone), 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 Fertility, pregnancy and lactation

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

Folic acid is excreted in breast milk.

4.7 Effects on ability to drive and use machines

There are no known effects of this preparation on the ability to drive or use machines.

4.8 Undesirable effects

Allergic reactions to folic acid have been reported.

Mild gastro-intestinal upsets are rare but may occur.

Anaphylactic reactions have been reported with frequency not known.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No cases of acute overdosage appear to have been reported, but even extremely high doses are unlikely to cause harm to patients.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: B03BB

After conversion into co-enzyme forms it is concerned in single carbon unit transfers in the synthesis of purines, pyrimidines and methionine.

5.2 Pharmacokinetic properties

About 70-80% of a 2mg oral solution of folic acid is absorbed. Larger doses are probably equally well absorbed. It is distributed into plasma and extracellular fluid. In plasma, folate is bound weakly to albumin (70%). There is a further high affinity binder for folate but this has a very low capacity and is barely detectable in normal sera. About 70% of small doses of folate (about 1mg) are retained and the rest excreted into the urine. With larger doses most is excreted into the urine. With a 5mg dose of folate, urinary excretion will be complete in about 5 hours. There is an enterohepatic circulation of folate. The retained folate is taken into cells and reduced by dihydrofolate to tetrahydrofolate. Folic acid is a relatively poor substrate for folate reduction, the normal substrate being dihydrofolate.

Folic acid itself does not occur in natural materials, it is entirely a pharmacological form of the compound. Once reduced, folate has additional glutamic acid residues added, a folate pentaglutamate being the dominant intracellular analogue. These polyglutamates are the active co-enzymes.

5.3 Preclinical safety data

Folic Acid is a drug on which extensive clinical experience has been obtained.

Relevant information for the prescriber is provided elsewhere in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol (E422)

Mannitol (E421)

Disodium phosphate, anhydrous

Sodium dihydrogen phosphate dihydrate

Disodium edetate

Methyl parahydroxybenzoate (E218)

Strawberry flavour (contains propylene glycol (E1520))

Purified water

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

9 Months

Discard 30 days after first opening.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C).

Keep the bottle in the outer carton in order to protect from light.

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Bottle: Type III Amber glass

Closure: Tamper-evident, child-resistant white plastic cap consists of polypropylene inner, polyethylene outer, expanded polyethylene (EPE) liner

Dosing Device: 10ml oral syringe with 0.5ml graduation and an adaptor.

Pack size: 150ml

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 39307/0083

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/01/2018

10 DATE OF REVISION OF THE TEXT

30/07/2020