

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Folic Acid 5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Folic Acid 5 mg.

Excipient(s) with known effect

Contains up to 97.10 mg lactose monohydrate per tablet.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Yellow to orange-yellow, speckled, round, biplane tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an essential ingredient for the production and maturation of red blood cells, in particular in such conditions as megaloblastic anaemia of infancy and of pregnancy, nutritional macrocytic anaemia, pellagra, sprue, post gastrectomy anaemia. As an adjunct in the management of pernicious anaemia.

Treatment of folic acid deficiency refractory to dietary measures.

4.2 Posology and method of administration

Adults

The usual daily dose is 10 to 20 mg with a maintenance dose of 2.5 – 10 mg.

Children

The usual daily dose is 5 - 15 mg.

Method of administration

Oral.

4.3 Contraindications

Folic acid should not be used as the only treatment of pernicious anaemia since alone it will not prevent the development of subacute combined degeneration of the spinal cord.

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

A rise in the reticulocyte count, induced by folic acid, may mask vitamin B₁₂ deficiency. Prior to treatment of megaloblastic anaemia, it should be ensured that this disorder is not as a result of vitamin B₁₂ deficiency, as there is a risk of irreversible neurological disorders. The aetiology of megaloblastic anaemia must be elucidated prior to initiating treatment.

4.4 Special warnings and precautions for use

Caution is advised for patients under therapy for folate-dependent tumours when taking folic acid.

Even in cases of life-threatening megaloblastic anaemia, the possibility of vitamin B₁₂ deficiency must be ruled out prior to initiating treatment, due to the risk of irreversible neurological disorders (by obtaining serum and erythrocyte samples and determining vitamin B₁₂ levels).

This product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Folic acid has been reported to decrease serum phenytoin and barbiturate antiepileptic levels. Susceptibility to seizures may be increased during anticonvulsive treatment.

If high doses are administered, it cannot be excluded that folic acid and co-administered folic acid antagonists – e.g. chemotherapeutic agents (trimethoprim, proguanil, pyrimethamine) and cytostatics (methotrexate) – might mutually inhibit their respective effects.

High doses of folic acid, if co-administered with fluorouracil, may result in severe diarrhoea.

Chloramphenicol can hinder the response to folic acid treatment, and should therefore not be administered to patients with symptoms of severe folic acid deficiency.

4.6 Fertility, pregnancy and lactation

Folic acid is indicated for the treatment of megaloblastic anaemia during pregnancy. There are no known risks for use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Folic acid is generally well tolerated. On rare occasions, gastro-intestinal disorders, sleep disturbances, agitation and depression are observed at very high doses. In isolated cases, hypersensitivity reactions may occur, e.g. erythema, pruritus, bronchospasm, nausea or anaphylactic shock.

Immune system disorders

Anaphylactic reaction: 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

(a) *Symptoms of overdosage*

Following chronic administration of very high doses (over 15 mg folic acid daily for more than 4 weeks), overdosage with folic acid manifests in the form of the following symptoms: bitter taste, loss of appetite, nausea, flatulence, nightmares, agitation, depression. The incidence and intensity of epileptic attacks may increase in patients receiving antiepileptic therapy (especially with Phenobarbital, phenytoin or primidone).

(b) Management of overdosage

No specific measures are necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamins, other combinations

ATC Code: A11JC

In man, an exogenous source of folate is required for nucleoprotein synthesis and maintenance of normal erythropoiesis. Folic acid, whether given by mouth or parenterally stimulates specifically the production of red blood cells, white blood cells and platelets in persons suffering from certain megaloblastic anaemias.

5.2 Pharmacokinetic properties

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 principle storage site is the liver. There is an enterohepatic circulation of folate; about 4 to 5 micrograms is excreted in the urine daily.

5.3 Preclinical safety data

Folic acid is not mutagenic. Massive doses in rats and in rabbits (100 mg.kg^{-1} upwards) produce precipitation of folate crystals in renal tubules, particularly proximal tubules and ascending limb of the Loop of Henle. Tubular necrosis is followed by recovery.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Cellulose powdered
Talc
Colloidal anhydrous silica
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

30 months

6.4 Special precautions for storage

Blister

Do not store above 25°C.
Store in the original package in order to protect from moisture.

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

6.5 Nature and contents of container

Blister packs consisting of white PVC/PVDC and hard temper aluminium foil contained in carton.

Pack sizes: 14, 28, 56, 84 and 98 tablets.

Not all pack sizes may be marketed.

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

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
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8 MARKETING AUTHORISATION NUMBER

PA0126/057/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 May 1988

Date of last renewal: 11 May 2008

10 DATE OF REVISION OF THE TEXT

May 2018