SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Folic Acid 0.4 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 0.40 mg Folic Acid BP (anhydrous).

Product contains lactose.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Appearance: Pale yellow, circular, biconvex tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Folic acid tablets 0.4 mg are indicated for the prevention of first occurrence neural tube defects in the foetus. For use by women who are planning a pregnancy.

4.2 Posology and method of administration

Adult females: One tablet (0.4mg) daily Supplementation should begin by taking one tablet (0.4 mg) daily prior to conception and be continued for at least the first 12 weeks of pregnancy.

Administration: Oral. The tablets should be swallowed with a drink of water.

4.3 Contraindications

1. Hypersensitivity to folic acid or any of the ingredients in this medicine.
2. Folic acid should not be given alone in the treatment of Addisonian pernicious anaemia and other vitamin B_{12} deficiency states, as this may precipitate the onset of subacute combined degeneration of the spinal cord.
3. Long term folate therapy is contra-indicated in any patient with untreated cobalamin deficiency. This can be untreated pernicious anaemia or other cause of cobalamin deficiency, including life long vegetarians. In elderly people, a cobalamin absorption test should be done before long-term folate therapy. Folate given to such patients for three months or longer has precipitated cobalamin neuropathy. No harm results from short courses of folate
4. Folic acid should not be used in malignant disease unless megaloblastic anaemia owing to folate deficiency is an important complication
5. Patients with folate-dependent tumour

4.4 Special warnings and precautions for use

Patients with vitamin B_{12} deficiency should not be treated with folic acid unless administered with adequate amounts of hydroxocobalamin, as it can mask the condition but the subacute irreversible damage to the nervous system will continue. The deficiency can be due to undiagnosed megaloblastic anaemia including in infancy, pernicious anaemia or macrocytic anaemia of unknown aethiology or other cause of cobalamin deficiency, including lifelong vegetarians.

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

Patients with rare hereditary problems of galactose intolerance, the total 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 status may be affected by a number of drugs:

- Antiepileptics: Folic acid can reduce plasma concentrations of anticonvulsants, particularly phenytoin, phenobarbital and primidone and therefore patients on anti- epileptic therapy may need to have their dose adjusted at regular intervals and should be under the supervision of a physician while taking folic acid supplements
- Antibacterials: chloramphenicol and co-trimoxazole may interfere with folate metabolism
- Sulfasalazine: can reduce the absorption of folic acid

- Preparations containing folic acid or its derivatives may decrease the effectiveness of methotrexate.

Patients with hypersensitivity to folic acid have been demonstrated to have antibodies that cross react with other folic acid analogues, including methotrexate, folinic acid (leucovorin) and aminopterin.

4.6 Fertility, Pregnancy and lactation

Pregnancy

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

The product is indicated for use during pregnancy. In normal use, the recommended dose of 400 μg of folic acid per day is not associated with deleterious effects during pregnancy and lactation.

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 vitamin 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

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

4.8 Undesirable effects

Gastrointestinal disorders **Rare (≥1/10,000 to <1/1,000)**	Anorexia, nausea, abdominal distension and flatulence
Immune system disorders	
Rare (≥1/10,000 to <1/1,000)	Allergic reactions, comprising erythema, rash, pruritus, urticaria, and dyspnoea.
Not known	Anaphylactic reaction

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 this kind have been reported, but even extremely high doses are unlikely to cause harm to the patient.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code BO3B B01

Folic Acid is essential in preventing megaloblastic anæmia especially if it is deficient in poor nutritional states, pregnancy or anti-epileptic patients.

Folic Acid has been demonstrated to prevent recurrence of neural tube defects, as well as to prevent first occurrence neural tube defect when taken in different doses of 4mg and 0.4mg respectively.

5.2 Pharmacokinetic properties

Folic acid is readily absorbed following oral dosage, and is extensively bound to plasma proteins.

5.3 Preclinical safety data

Studies have shown that while it is possible to produce toxicity with very large doses of folate in rats, by precipitation of folate in renal tubules, this effect is not relevant in the proposed uses or doses.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose PhEur
Maize Starch PhEur
Pregelatinised Starch BP
Magnesium Stearate PhEur
Purified Water PhEur (Not detected)

6.2 Incompatibilities

None stated.

6.3 Shelf life

3 years

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Blister packs consisting of 250 µm clear PVC and 20 µm hard temper aluminium foil contained in a carton.
Pack sizes: 28, 56, 84, 90, 98 and 100 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Relonchem Limited
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Widnes
WA8 0RP

8 MARKETING AUTHORISATION NUMBER(S)

PL 20395/0106

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/03/2009

10 DATE OF REVISION OF THE TEXT

27/09/2021