Summary of Product Characteristics

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Folic Acid 5 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 QUALITATIVE DECLARATION

Folic acid Ph.Eur

2.2 QUANTITATIVE DECLARATION

Each uncoated tablet contains
Folic acid Ph.Eur 5 mg
Excipients q.s
For full list of excipients see Section 6.1

3. PHARMACEUTICAL FORM

Description: Yellow colour, round shaped biconvex uncoated tablets plain on both sides.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATION

Folic acid is a component of the B group of vitamins and is necessary for the normal production and maturation of red blood cells.

1. For the treatment of folate-deficient megaloblastic anaemia due to malnutrition, malabsorption syndromes (such as coeliac disease or sprue) and increased utilisation as in pregnancy. It should not be used alone in undiagnosed megaloblastic anaemia including in infancy, pernicious anaemia or macrocytic anaemia of unknown aetiology, unless administered with adequate amounts of hydroxocobalamin.

2. For the prophylaxis of drug induced folate deficiency e.g. caused by administration of phenytoin, phenobarbital and primidone.

3. For the prophylaxis against folate deficiency in chronic haemolytic states or in renal dialysis

4. For the prevention of neural tube defects for woman planning a pregnancy and known to be at risk.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Posology
Adults (including the elderly)

In folate deficient megaloblastic anaemia: 5mg daily for 4 months; up to 15mg daily may be necessary for malabsorption states.

In drug induced folate deficiency: 5mg daily for 4 months; up to 15mg daily may be necessary for malabsorption states.

For prophylaxis in chronic haemolytic states or in renal dialysis: 5mg every 1-7 days depending on underlying disease.

Prevention of neural tube defects in women known to be at risk: 5mg daily started before conception and continued throughout the first trimester.

Pregnancy:
In established folate deficiency: 5mg daily continued to term.

Paediatric population
For young children a more suitable dosage form should be used.
In folate deficient megaloblastic anaemia:

Child 1-18 years 5mg daily for 4 months; maintenance 5mg every 1-7 days.
In haemolytic anaemia; metabolic disorders:

Child 1-12 years 2.5mg-5mg once daily.
Child 12-18 years 5-10mg once daily.

Prophylaxis of folate deficiency in renal dialysis:
Child 1-12 years 250 microgram/kg (max 10mg) once daily.

Children 12-18 years 5-10mg once daily.

Method of administration
For oral administration

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substance or to 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
- Folic acid should never be given alone in the treatment of Addisonian pernicious anaemia and other vitamin B12 deficiency states because it may precipitate the onset of subacute combined degeneration of the spinal cord
- Folic acid should not be used in malignant disease unless megaloblastic anaemia owing to folate deficiency is an important complication

4.4 SPECIAL WARNINGS & 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.
- This product is not intended for healthy pregnant women where lower doses are recommended, but for pregnant women with folic acid deficiency or women at risk for the reoccurrence of neural tube defects.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

- There is a specific interaction between phenytoin and folate such that chronic phenytoin use produces folate deficiency. Correction of the folate deficiency reduces plasma phenytoin with potential loss of seizure control. Similar but less marked relationship exist with all anti-convulsant treatments including sodium valproate, carbamazepine and the barbiturates (including phenobarbital and primidone). Sulphasalazine and triamterene also inhibit absorption.
- Antibacterials – chloramphenicol and co-trimoxazole may interfere with folate metabolism.
- Folic acid may interfere with the toxic and therapeutic effects of methotrexate. Methotrexate and trimethoprim are specific anti-folates and the folate deficiency caused by their prolonged use cannot be treated by Folic Acid Tablets BP.
- Folate supplements enhance the efficacy of lithium therapy.
- Folinic acid should be used.
- Nitrous oxide anaesthesia may cause an acute folic acid deficiency.
- Both ethanol and aspirin increase folic elimination.

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.

Breast-feeding
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
No effect on concentration and co-ordination.

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, dyspnoea, and anaphylactic reactions (including shock).

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 TMDA ADR reporting tool; website: https://imis.tmda.go.tz/arrt or search for TMDA Adverse Reactions Reporting Tool in the Google Play Store.

4.9 OVERDOSE

No special procedures or antidote are likely to be needed.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES
Pharmacotherapeutic group: folic acid and derivatives, ATC Code BO3B B01

Folic acid is a member of the vitamin B group which is reduced in the body to tetrahydrofolate, a co-enzyme active in several metabolic processes and produces a haemopoietic response in nutritional megaloblastic anaemias (but see warning in Section 4.4 regarding need for concomitant use of hydroxycobalamin). Folic acid is rapidly absorbed and widely distributed in body tissues.

It is used in the treatment and prevention of folate deficiency states.

Pharmacokinetics:
Absorption
Folic acid is rapidly absorbed from the gastrointestinal tract, mainly from the proximal part of the small intestine. Dietary folates are stated to have about half the bioavailability of crystalline folic acid. The naturally occurring folate polyglutamates are largely deconjugated and reduced by dihydrofolate reductase in the intestine to form 5-methyltetrahydrofolate (5MTHF). Folic acid given therapeutically enters the portal circulation largely unchanged, since it is a poor substrate for reduction by dihydrofolate reductases.

Distribution
Via portal circulation. 5MTHF from naturally occurring folate is extensively plasma bound. The principal storage site of folate is in the liver; it is also actively concentrated in the CSF. Folate is distributed into breast milk.

Biotransformation
Therapeutically given folic acid is converted into the metabolically active form 5MTHF in the plasma and liver. There is an enterohepatic circulation for folate.

Elimination
Folate metabolites are eliminated in the urine and folate in excess of body requirements is excreted unchanged in the urine. Folic acid is removed by haemodialysis.

5.3 PRE-CLINICAL SAFETY DATA:

Not applicable.

6. PHARMACEUTICAL PARTICULARS
6.1 LIST OF EXCIPIENTS:
Active ingredients: Folic acid Ph.Eur
Inactive ingredients: Microcrystalline cellulose Ph.Eur, Maize Starch Ph.Eur, Magnesium stearate Ph.Eur, Colloidal Anhydrous silica Ph.Eur.

6.2 INCOMPATIBILITIES
None stated.

6.3 SHELF LIFE
24 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE
Do not Store above 30ºC, store in dry place. Protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER
10 tablets in a Alu - PVC blister, 3 such blisters in carton along with the pack insert.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING
Not Applicable

6.7 FOR DISPOSAL AND OTHER HANDLING
Not Applicable

7.MARKETING AUTHORIZATION HOLDER
AKRITI PHARMACEUTICALSPVT LTD.
Office No.205,Thane mint,Indiabulls,Behind Hiranandani Meadows.
Near Hyde Park,off.Gladys Alvaris Road,
Thane (W)-400610
Mumbai.
E-mail: info1@akritipharma.com

8. MARKETING AUTHORIZATION NUMBER

TAN 22 HM 0263

9. DATE OF <REGISTRATION> / <RENEWAL OF REGISTRATION>

19th July, 2022

10. DATE OF REVISION OF THE TEXT

11. LEGAL CATEGORY
Prescription only medicine