SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

Be-Tabs Folic Acid 5 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Folic acid 5mg

Contains sugar: Lactose monohydrate 52,4 mg per tablet

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet

Yellow – orange tablet, 5,5mm in diameter with a score mark on the one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Folic acid is indicated for the prophylaxis and treatment of megaloblastic anaemia.

4.2 Posology and method of administration

The recommended daily dietary allowance of folate is 400 mcg for adults and adolescents. In the treatment of megaloblastic anaemia, folic acid may be given by mouth in an initial dose of 10 to 20 mg daily for 14 days; the maintenance dose is 2,5 to 10 mg.

In the prophylaxis of megaloblastic anaemia of pregnancy, the usual dose is 200 to 500 mcg daily

Method of Administration

For oral use.

4.3 Contraindications

- Hypersensitivity to folic acid or to any of the excipients listed in section 6.1.
- Folic acid should never be given alone or in conjunction with inadequate amounts of hydroxycobalamin for the treatment of megaloblastic or pernicious anaemia.

4.4 Special warnings and precautions for use

Folic acid should never be given alone or in conjunction with inadequate amounts of hydroxycobalamin for the treatment of megaloblastic or pernicious anaemia.

BE-TABS FOLIC ACID 5 mg TABLETS contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

- 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 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.

Non-medicine - 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 medicines 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

System Organ Class	Frequency	Adverse Reaction
Gastrointestinal disorders	Less Frequent	Anorexia, nausea, abdominal distension and flatulence
Immune system disorders	Less Frequent	Allergic reactions, comprising erythema, rash, pruritus, urticaria, dyspnoea, and anaphylactic reactions (including shock).

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting form",** found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/index/8

4.9 Overdose

Large and continuous doses of folic acid may lower the blood concentration of vitamin B12. Larger amounts of folate are rapidly excreted in the urine.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.22.1.4 Vitamins, other.

Vitamin supplement.

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.

5.2 Pharmacokinetic properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Lactose monohydrate
- Magnesium stearate
- Microcrystalline cellulose
- Starch maize

6.2 Incompatibilities

None known.

6.3 Shelf life

36 Months – 28, 100, 500, 1000, 5000 and 10 000 tablets.

15 Months – Patient ready packs of different pack sizes.

6.4 Special precautions for storage

Store in a cool, dry place, at or below 25ºC and protect from light.

6.5 Nature and contents of container

In bottles of 28, 100, 500, 1000, 5000 and 10 000 tablets. Patient ready packs of different pack sizes.

6.6 Special precautions for disposal

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill Ext.1

Roodepoort, 1724

South Africa

8. REGISTRATION NUMBER(S)

T1205 (Act 101 / 1965) (S.A.)

S2 BOT 0500769 (Botswana Reg. No.) (1000's and 5000's)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

SEPTEMBER 1985

10. DATE OF REVISON OF THE TEXT

21 October 2022