SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Folic Acid Tablets BP 5 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Folic Acid hydrate 5 mg

Excipients with known effect

50.4 mg lactose & 2.8 mg sucrose per tablet

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablets

Plain yellow, round uncoated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

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.

For the prophylaxis of drug induced folate deficiency e.g. caused by administration of phenytoin, phenobarbital and primidone. (See section 4.5).

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

For the prevention of neural tube defects for woman planning a pregnancy and known to be at risk. (See section 4.6).

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 folic acid hydrate or to any of the excipients listed in section 6.1.

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 B_{12} 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 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.

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.

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

This product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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). Sulfasalazine 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-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 or 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): Not known:	Allergic reactions, comprising erythema, rash, pruritis, urticaria, dyspnoea Anaphylactic reaction

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

There are no specific symptoms of overdosage and similarly no emergency treatment or antidotes. Metabolism and excretion can be rapid.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

B03B B01 – Folic Acid and Derivatives

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 the need for concomitant use of hydroxo-cobalamin). Folic acid is rapidly absorbed and widely distributed in body tissues.

5.2 Pharmacokinetic properties

Folic acid is readily absorbed mainly from the small intestine. It rapidly appears in the blood and there is considerable plasma protein binding. Excretion is of the order of 4-5µg daily in the urine, for subjects on normal diets.

5.3 Preclinical safety data

There is no preclinical safety data of relevance to the prescriber which is additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Pregelatinised Maize Starch
Sucrose
Stearic Acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Tablet containers: Do not store above 25°C. Keep the container tightly closed.
Blisters: Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

HDPP tablet containers with LDPE lids containing 50, 100, 500 or 1000 tablets.

Al/PVC/PVDC blisters enclosed in an outer carton, containing 28 or 56 tablets.

Al/PVC/PVDC blisters enclosed in an outer carton – “Burgopak” packaging format, containing 28 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No specific instructions.

7 MARKETING AUTHORISATION HOLDER

Kent Pharma UK Limited
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Ashford, Kent, England, TN23 1FB.

8 MARKETING AUTHORISATION NUMBER(S)

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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