Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Preconceive 400 microgram Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 400 micrograms Folic Acid.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Cream/yellow, circular, biconvex, uncoated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the prevention of first occurrence of neural tube defect in all women who are planning a pregnancy.

4.2 Posology and method of administration

All women planning a pregnancy should take 0.4 mg (400 mcg) folic acid daily before conception and until the end of the third month of pregnancy. Women who have not been taking folic acid supplements and who suspect that they are pregnant should begin to take Preconceive Tablets at once and continue until week 12 of pregnancy.

4.3 Contraindications

1. Should not be taken by people having folate dependent tumours.

2. Vitamin B_{12} deficiency.

4.4 Special warnings and precautions for use

Preconceive Tablets are not intended be given alone in the treatment of Addisonian pernicious anaemia or other B12 deficiency states, as the onset of sub-acute degeneration of the spinal cord might thereby be precipitated. Keep out of the sight and reach of children. Store in a cool dry place.

4.5 Interaction with other medicinal products and other forms of interaction

Folic acid reduces plasma phenytoin, phenobarbital and primidone concentrations. Consequently patients on anti epileptic therapy should have their dose adjusted at regular intervals and be supervised by the physician.

4.6 Fertility, pregnancy and lactation

While it is possible to produce toxicity with huge doses of folate in rats, by precipitation of folate in the renal tubes this effect is not relevant in the proposed dosages. It has been demonstrated in many studies that 4 mg of folic acid taken before and during the first trimester of pregnancy will prevent recurrence of neural tube defects. Folic acid is excreted in breast milk, however, problems in humans have not been documented with intake of normal daily requirements.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Folic acid is generally well tolerated. Gastro-intestinal disturbances may occur. Hypersensitivity reactions have been reported rarely.

Severe allergic reaction (anaphylactic reaction) may occur. The frequency is unknown.

4.9 Overdose

Overdose is not normally a problem. Folic acid is stored in the liver and cerebrospinal fluid. Any excess to requirement is excreted in the urine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Folic acid is essential in preventing megaloblastic anaemia, especially if it is deficient in poor nutritional states, pregnancy or 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 4 mg and 0.4 mg respectively.

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 for folate; about 4 to 5 micrograms is excreted in the urine daily. Administration of larger doses of folic acid leads to proportionately more of the vitamin being excreted in the urine. Folic acid is distributed into breast milk.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Anhydrous calcium hydrogen phosphate
Maize starch
Magnesium stearate
Stearic acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 Years.

6.4 Special precautions for storage

Do not store above 25°C .
Store in the original package.

6.5 Nature and contents of container

Three foil blisters of 20 tablets (or two foil blisters of 30 tablets) in a cardboard carton with a leaflet.
Three foil blisters of 30 tablets in a cardboard carton with a leaflet.
Blisters are manufactured form Food grade PVC and Aluminium/Polyethylene laminate.
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.

7 MARKETING AUTHORISATION HOLDER

G. R. Lane Health Products Limited
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8 MARKETING AUTHORISATION NUMBER

PA0257/055/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 July 1997

Date of last renewal: 24 July 2007

10 DATE OF REVISION OF THE TEXT

May 2018