

IBERET FOLIC®-500

CONTROLLED-RELEASE IRON WITH B-COMPLEX AND VITAMIN C

Filmtab Tablets

NAME OF PRODUCT

Iberet Folic 500 Controlled-Release Iron with B-Complex and Vitamin C Filmtab Tablets.

DESCRIPTION OF PRODUCT

Iberet Folic 500 is an Abbott hematinic containing iron in the Gradumet controlled-release vehicle; vitamin C for enhancement of iron absorption and the B-complex vitamins including Folic Acid. The Iberet Folic 500 Filmtab is for oral use.

Each Filmtab tablet provides:

Ferrous Sulfate*	525mg
(equivalent to 105mg of elemental iron)	
Vitamin C (Ascorbic Acid)	500mg
Niacinamide	30mg
Calcium Pantothenate	10mg
Vitamin B1 (Thiamine Mononitrate)	6mg
Vitamin B2 (Riboflavin)	6mg
Vitamin B6 (Pyridoxine Hydrochloride)	5mg
Vitamin B12 (Cyanocobalamin)	25mcg
Folic acid	800mcg

* in controlled-release form (Gradumet)

Inactive Ingredients

Polyethylene glycol, magnesium stearate, povidone, methacrylic acid & methyl methacrylate, magnesium oxide, FD&C Blue No.1, talc, stearic acid, polyvinyl alcohol, titanium dioxide, FD&C Red No.7, lecithin, xanthan gum, FD&C Blue No. 2, hypromellose.

WHAT IS THIS MEDICINE USED FOR?

Iberet Folic 500 is indicated in non-pregnant adults for treatment of iron deficiency and prevention of concomitant folic acid deficiency where there is an associated deficient intake or increased need for the B-complex vitamins. Iberet Folic 500 is also indicated in pregnancy for the prevention and treatment of iron deficiency where there is a concomitant deficient intake or increased need for the B-complex vitamins (including folic acid).

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Iberet Folic 500 is administered orally. Usual adult dose, including pregnant females: One tablet daily, or as directed by a physician. The tablets should not be sucked, chewed or kept in the mouth, but swallowed whole with water. Tablets should be taken before meals or during meals, depending on gastrointestinal tolerance.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

Known sensitivity to any of its ingredients. Repeated blood transfusions or parenteral iron therapy contraindicate concurrent oral iron therapy. Iberet Folic 500 is contraindicated in the rare instance of hypersensitivity to folic acid and in patients with pernicious anaemia.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

Where anaemia exists, its nature should be established and underlying causes determined. Due to the risk of mouth ulcerations and tooth discolouration, tablets should not be sucked, chewed or kept in mouth, but swallowed whole with water. In older patients and those tending to lead to vitamin B12 depletion, serum B12 levels should be regularly assessed during treatment with Iberet Folic 500. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucosegalactose malabsorption should not take this medicine.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILST TAKING THIS MEDICINE?

Antacids may decrease iron absorption. Ferrous sulphate may interfere with the absorption of tetracyclines. The antiparkinsonism effects of levodopa may be reversed by pyridoxine. Iron absorption is inhibited by the ingestion of eggs or milk.

SIDE EFFECTS

Post marketing: The following adverse drug reactions have been reported during post-marketing surveillance. The frequency of these reactions is considered not known (cannot be estimated from the available data).

Ferrous sulfate

Immune system disorders: allergic reaction from rash to anaphylaxis

Gastrointestinal disorders: Injury to mouth and pharynx (throat), mouth ulceration (in cases of incorrect use, when tablets are chewed, suck or left in the mouth), esophageal ulcer (i.e ulcer on the tube that connects your mouth with your stomach), nausea, vomiting, abdominal pain or discomfort hematemesis, blackening of stools, diarrhea constipation, ileus.

Elderly patients and patients with difficulty swallowing may also be at risk of ulceration of the throat, oesophagus (the tube that connects your mouth with your stomach) or bronchus (the major air passages of the lungs) if the tablet enters the airways.

The likelihood of gastric intolerance to iron in the controlled-release Gradumet vehicle is remote. If such should occur, the tablet may be taken after a meal.

Vitamin C (Ascorbic Acid)

Ascorbic acid is usually well tolerated. However, large doses are reported to cause diarrhea and other gastrointestinal disturbances and are associated with the formation of renal calcium oxalate calculi.

Folic acid

Immune system disorders: Hypersensitization has been reported following both oral and parenteral administration of folic acid.

SIGNS AND SYMPTOMS OF OVERDOSE

Close tightly and keep out of reach of children. Contains iron, which can be harmful or fatal to adults and children in large doses. Hepatic necrosis and hepatic failure may develop. In case of accidental overdose, seek professional assistance immediately.

HOW SHOULD YOU KEEP THIS MEDICINE?

Store below 30°C. Keep out of reach of children.

WHEN SHOULD YOU CONSULT YOUR DOCTOR OR PHARMACIST?

For further information, please consult your doctor or pharmacist.

MANUFACTURED BY:

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