

Mediflic® Tablets

(Iron Polymaltose Complex + Folic Acid)

Composition

Each chewable tablet contains:

Iron (III)-hydroxide polymaltose complex (Mediate spec.) equivalent to

Elemental iron... 100mg

Folic Acid..... 350mcg

Description

The iron (III)-hydroxide polymaltose complex (IPC) is a water-soluble iron oxide macromolecular complex of polynuclear iron (III)-hydroxide and partially hydrolyzed dextrin (polymaltose).

The polynuclear iron (III)-hydroxide cores are superficially surrounded by a number of non-covalently bound polymaltose molecules resulting in an overall complex molecular mass of approximately 52,300 Daltons. This molecule is so large that diffusion through the membrane of the mucosa is about 40 times smaller than the one for the hexaquo-iron (II) unity. The complex is stable and does not release ionic iron under physiological conditions. The iron in the polynuclear “cores” is bound in a similar structure as in the case of physiologically occurring ferritin.

Due to these chemical and pharmacological properties IPC is suitable for oral iron substitution.

Properties

Iron polymaltose as present in Mediflic tablet provides an ideal preparation for all iron deficiency anaemias, it is rapidly absorbed with a high rate of iron utilization and produces an effective increase in haemoglobin. Folic Acid is necessary for the normal production of red blood cells, including maturation of megaloblasts into normoblasts. Due to its favourable non-ionic nature Mediflic has the following properties unlike ionized iron salt preparations. Mediflic does not give rise to irritation of intestinal mucosa and does not stain the teeth. Mediflic has excellent tolerance.

Clinical Particulars

Therapeutic Indication:

- Prevention and Treatment of iron deficiencies, particularly iron deficiency anaemia.
- Prevention of iron and folic acid deficiency before, during and after pregnancy (during lactation)

Posology and methods of administration

Dosage and duration of therapy are dependent upon the extent of iron deficiency. The daily dose can be divided into separate doses or can be taken at one time during or after meal.

In case of manifested iron deficiency the therapy takes about 3-5 months until normalization of the haemoglobin value is achieved. Afterwards the therapy should be continued for several weeks with a dosage such as described for latent iron deficiency to replenish the iron stores.

Dosage for Children (6-12 years):

100mg (1 tablet) daily

Dosage for Children (above 12 years), Adults and Nursing Women:

Manifested Iron Deficiency..... 100-300mg (1-3 tablets) daily

Latent Iron Deficiency..... 100 mg (1 tablet) daily

Dosage During Pregnancy:

Manifested Iron Deficiency.....	100-300mg (1-3 tablets) daily
Latent Iron Deficiency	100mg (1 tablet) daily
Prophylactic Therapy (RDA)	50-100mg (1/2 tablet) daily

Contra- Indications

Iron overload (e.g haemochromatosis, haemosiderosis) or disturbances in iron utilization (e.g lead anaemia, sidero achrestic anaemia, thalassaemia) and anaemias not caused by iron deficiency (e.g haemolytic anaemia). Hypersensitivity to iron or folic acid.

Interactions

There is no interaction between Mediflic and food or between Mediflic and drugs due to its non-ionic nature.

Pregnancy and Lactation

Reproduction studies in animals did not show any foetal risk. Controlled studies in pregnant women after the first trimester have not shown any undesirable effects on mothers and neonates. There is no evidence of a risk during the first trimester and the possibility of a negative influence to the foetus is unlikely to occur.

Mother's milk contains iron bound to lactoferrin. It is not known how much iron from the complex is passed into mother's milk. The administration of IPC is unlikely to cause undesirable effects to the nursed child. During pregnancy and lactation IPC should be used on prescription.

Undesirable effects

Occasionally gastro-intestinal irritations such as sensation of repletion, pressure in the epigastric region, nausea, constipation or diarrhoea can occur. A dark coloration of the stool is of no clinical significance.

Overdose

In the cases of overdose neither intoxication nor iron overload have been reported upto date.

Instruction

Store below 25°C.

Protect from sunlight & moisture.

Keep medicines out of the reach of children.

Dosage

As prescribed by the physician.

Presentation

Mediflic chewable tablets are available in blister pack of 10's.

Manufactured by:

Mediate Pharmaceutical (Pvt) Ltd.
150/151, Sector 24, Korange Industrial
Area, Karachi, Pakistan
Mfg. Lic. No.: 000167



Marketed by:

OBS Pharma (Pvt) Ltd.
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