

# National Agency for Food & Drug Administration & Control (NAFDAC)

**Registration & Regulatory Affairs (R & R) Directorate**

**SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE**

1. **NAME OF THE MEDICINAL PRODUCT**

Mumfer Chewable tablets (Iron (III) hydroxide polymaltose complex + Folic acid Tablets)

1. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each uncoated chewable tablet contains:

Iron (III) Hydroxide Polymaltose Complex IH

Equivalent to Elemental Iron 100 mg

Folic Acid BP 500 mcg

Appropriate overages of vitamins added to compensate for loss on storage

For a full list of excipients, see section 6.1.

1. **PHARMACEUTICAL FORM**

Chewable Tablets

Brown coloured, speckled, round, biconvex, uncoated tablets having chocolate flavor and sweet taste.

1. **CLINICAL PARTICULARS**
	1. **Therapeutic indications**

For prophylaxis of iron and folic acid deficiency during pregnancy

* 1. **Posology and Method of Administration**

Adults only:

1 tablet a day throughout pregnancy.

Tablets may be chewed.

Route of administration:

Oral.

* 1. **Contraindications**

Use in patients with a known hypersensitivity to any of the active ingredients.

Use in patients with anaemia of undiagnosed aetiology.

* 1. **Special Warnings and Precautions for Use**

This product should be used with caution in patients with haemochromatosis and haemolytic anaemias.

* 1. **Interaction with other medicinal products and other forms of interaction**

The absorption of iron salts is decreased in the presence of antacids.

Iron chelates with tetracyclines, absorption of both agents may be impaired.

* 1. **Pregnancy and lactation**

No information available

* 1. **Effects on ability to drive and use machines**

No information available

* 1. **Undesirable effects**

Side effects include nausea, diarrhoea, constipation may occur rarely.

* 1. **Overdose**

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Symptoms of overdosage with iron salts include nausea and vomiting, abdominal pain, vomiting of blood and circulatory collapse. In severe cases, encephalopathy, acute hepatic necrosis and acute renal failure may develop after a latent period.

Treatment consists of gastric lavage followed by the introduction of 5 g desferrioxamine into the stomach. Serum iron levels should be monitored. In severe cases intravenous desferrioxamine should be administered together with supportive and symptomatic measures as required.

1. **PHARMACOLOGICAL PROPERTIES**
	1. **Pharmacodynamic properties**

A haematinic with added folic acid.

* 1. **Pharmacokinetic properties**

A haematinic with added folic acid.

* 1. **Preclinical safety data**

No information available.

1. **PHARMACEUTICAL PARTICULARS**
	1. **List of excipients**

List of excipients are Lactose Monohydrate, Colloidal Silicon Dioxide, Isopropyl alcohol, Methylene chloride, Ethy cellulose, Sugar Sucrose, Mannitol, Dextrose anhydrous, Cocoa powder, Aspartame, Methyl Parahydroxybenzoate, Propyl Hydroxybenzoate, Sodium starch glycolate, Crosscarmellose sodium, Taste essential everfresh 101 vanilla, Trusil chocolate special, Purified talc, Purified water, Magnesium stearate, Povidone

* 1. **Incompatibilities**

None.

* 1. **Shelf life**

30 Months

* 1. **Special precautions for storage**

Store below 25°C. Protect from moisture and light.

* 1. **Nature and contents of container**

A printed carton containing an insert and 3 printed aluminum stips each containing 10 brown coloured, speckled, round, biconvex, uncoated tablets having chocolate flavor and sweet taste.

* 1. **Special precautions for disposal and other handling**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7. <APPLICANT/MANUFACTURER**

Glenmark Pharmaceuticals Limited,

B/2, Mahalaxmi Chambers, 22, Bhulabhai Desai road, Mumbai – 400 026

+91-253-6613999

Anurag.Sharma@glenmarkpharma.