

# Ferol-TR®

Iron+Folic acid+Zinc

## Description

**Ferol-TR®** is a combined preparation of Ferrous Sulphate, Folic Acid and Zinc. Three ingredients are mixed judiciously to achieve the maximum therapeutic response. These three are very important components for pregnant women, lactating mother and menstruating women.

## Composition

**Ferol-TR® Capsule:** Each timed-release capsule contains dried Ferrous Sulphate BP 150 mg (equivalent to 47 mg elemental Iron), Folic acid USP 0.5 mg and Zinc Sulphate Monohydrate USP 61.80 mg (equivalent to 22.53 mg elemental Zinc).

## Indications

**Ferol-TR®** is a combined preparation of Iron, Folic acid and Zinc, specially formulated for timed release over several hours. **Ferol-TR®** is indicated for the treatment and prophylaxis of Iron, Folic acid and Zinc deficiency specially during pregnancy and lactation.

## Dosage and administration

1 capsule daily. In more severe cases, 2 capsules daily or as directed by the physician.

## Contraindications

Do not use in patients hypersensitive to the components of the product or those with Iron overload.

## Side effects

Dark stools are usual during iron therapy, and nausea and other symptoms of gastrointestinal irritation, such as anorexia, vomiting, discomfort, constipation and diarrhoea are sometimes encountered. Zinc may also produce gastrointestinal upset. These timed-release capsules are designed to reduce the possibility of gastrointestinal irritation. There have been rare reports of allergic reactions.

## Use in pregnancy and lactation

Use of the drug during the first trimester of pregnancy should be avoided if possible. Thus administration of iron during the first trimester requires definite evidence of iron deficiency. Prophylaxis of iron deficiency where inadequate diet calls for supplementary Zinc and Folic acid is justified during the remainder of pregnancy.

## Precautions

During treatment care should be taken in patients who may develop iron overload, such

as those with haemochromatosis, haemolytic anaemia or red cell aplasia. Failure to respond to treatment may indicate other causes of anemia and should be further investigated.

## Drug interactions

Iron and Zinc chelate with tetracycline and absorption of all three agents may be impaired. Absorption of iron may be impaired by penicillamine and by antacids. Such potential interactions can be reduced by separating administration of each product by several hours. In patients with renal failure a risk of zinc accumulation could exist.

## Overdosage

Iron overdose is dangerous, particularly in children, and requires immediate attention. Gastric lavage should be carried out in the early stages, or if this is not possible, vomiting should be induced. These procedures should not be undertaken where signs of the corrosive effects of zinc are present. Give oral desferrioxamine (2 g for a child or 5 g for an adult and demulcent. If serum iron levels at 4 hours or more post-ingestion are over 5 mg/l in a child or 8 mg/l in an adult, or if the patient is in shock of coma, intravenous desferrioxamine should be used. Zinc sulphate in gross overdose is corrosive. Symptoms are those of gastrointestinal irritation, leading in severe cases to haemorrhage, corrosion of the mucosa and possible later stricture formation. Gastric lavage or emesis should be avoided. Demulcents such as milk should be given. Chelating agents such as dimercaprol, penicillamine or edetic acid have been recommended. Symptomatic and supportive measures should be given as required. The timed-release capsule presentation may delay excessive absorption of iron and zinc and allow more time for initiation of appropriate counter-measure.

## Storage

Store in a cool (Below 25° C temperature) and dry place protected from light.

## Packaging

**Ferol-TR® Capsule:** Each carton contains 15X2 capsules in blister pack.

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