

**Read all of this leaflet carefully before you start taking this medicine**

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**Form and presentation**

Coated tablets: Box of 30 coated tablets in alu strip of 10 tablets.

Syrup: Bottle of 150 ml.

**Composition****Coated tablets:**

Ferrous fumarate: 308 mg equivalent to 100 mg of elemental iron

Folic acid: 4 mg

Ascorbic acid: 200 mg

Excipients: maize starch, sucrose, purified talc, magnesium stearate, bees wax, colour chocolate supra (E110, E133, E124), gelatine, shellac.

**Syrup:**

Each 5 ml contains:

Iron: 50 mg as Iron (III) Hydroxide Polymaltose

Folic acid: 2 mg

Ascorbic acid: 100 mg

Excipients: xanthan gum, sodium methyl hydroxybenzoate (E219), sodium propyl hydroxybenzoate (E217), sodium benzoate (E211), sorbitol solution, liquid glucose, disodium edetate, saccharin sodium, colour Ponceau 4R supra (E124), essence raspberry, sodium hydroxide, purified water.

**Properties**

Fercefol is a preparation against anaemia that combines iron, folic acid and vitamin C.

Iron is an essential constituent required for haemoglobin formation and the oxidative process of living tissues.

Folic acid is essential as coenzyme into different metabolic processes, maturation and regeneration of hematopoiesis.

Vitamin C increases gastro intestinal iron absorption.

**Indications**

- Curative treatment of siderotic anaemia (minimum 4 to 6 months of treatment in association with an etiologic treatment).
- Preventive treatment of iron-deficiency in exposed subjects: pregnant women, unbalanced food diets (old patients, vegetarians, vegetaliens, mental anorexia), chronic bleeding.
- Megaloblastic anaemia by lack of folic acid.
- Chronic disorder of intestinal absorption (malabsorption, celiac disease, strong digestive resection).
- Lack of folate: malnutrition, chronic alcoholism.

**Administration and use**

Always take Fercefol exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

This medicine must be taken by oral route.

**Tablet:**

To be taken before meal with a glass water.

**- In the treatment of iron-deficiency anaemia:**

Adult: 1 tablet per intake, 1 or 2 times a day during 4 to 6 month in association with etiologic treatment. Equivalent to 100 to 200 mg of elemental iron and to 4 to 8 mg of folic acid daily.

- Maintenance dose in adults: 1 tablet daily.

**Syrup:**

Syrup formulation is more appropriate in children.

To be taken before meal based on digestive tolerance.

**- In the treatment of iron-deficiency anaemia:**

Adult: 1 to 2 measures of 5 ml per intake, 1 or 2 times a day during 4 to 6 months in association with etiologic treatment. i.e. 50 to 200 mg of elemental iron equivalent to 2 to 8 mg of folic acid daily

Children and new-borns: the intake is based on the iron dosage in the body. 6 to 10 mg/k/day in 1 or 2 intakes during at least 4 to 6 months in association with etiologic treatment.

- Maintenance dose in adults: 1 to 2 measures of 5ml daily.

**Contra-indications**

. Martial overload.

- . Isolated use in vitamin B12 deficiency.
- . Sensitivity to one of the components.
- . megaloblastic anaemia without diagnostic.

## **Warnings**

The excessive and prolonged use or the combination with other ferrous preparations can induce iron intoxication.

This formulation must be administered with caution to epileptic patients under treatment.

## **Precautions of use**

Fercefol treatment requires first a causal diagnostic.

Fercefol tablet contains sucrose, Fercefol syrup contains sorbitol and liquid glucose; if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

## **Effects on ability to drive and use machines**

Fercefol has no influence on this kind of activity.

## **Pregnancy and breastfeeding**

Fercefol does not represent any risk for pregnant and breastfeeding women at prescribed doses.

## **Drug interactions**

Please inform your doctor or your pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

- Iron absorption is impaired when associated with anti-acidity stomach drugs.
- The concomitant administration of tetracycline reduces the resorption (a suitable interval of 2 or 3 hours is therefore required between the intakes).
- Iron salts reduce the absorption and bioavailability of other drugs; among them the levodopa, the methyldopa, the penicillamine and fluoroquinolones like ciprofloxacin and ofloxacin.
- Some food components like phytines (coming from cereals) or phosphates can generate insoluble compounds with iron.
- Zinc salts can reduce absorption of iron.
- An excessive consumption of tea can inhibit the absorption of iron.
- The resorption of folic acid is reduced by ethanol and phenytoine.
- Barbiturics, cycloserine and oral contraceptives induce a decrease in the plasma concentration of folic acid.
- Folic acid antagonists such as methotrexate, pyrimethamine, trimethoprim and triamterene can induce anaemia.
- Folic acid has an antagonist action with sulfamides.
- Some tuberculostatic drugs can interfere with the folic acid action.

## **Adverse effects**

Like all medicines, Fercefol can have side effects.

Gastro-intestinal irritation and abdominal pain with nausea and vomiting are rare. Other effects include diarrhoea or constipation.

The faeces of patients taking iron salts may be coloured black.

## **Overdosage**

If you have taken too much Fercefol, contact immediately your doctor, your pharmacist or the poison unit.

Folic acid and vitamin C are relatively non-toxic substances.

Symptoms of intoxication due to an overdosage of iron are the following: diarrhoea, nausea, blood-stained vomiting and shock.

Immediate transfer to hospital is required.

The treatment in hospital is based on gastro-intestinal evacuation and the antidote is the deferoxamine with symptomatic reanimation.

## **Storage**

Keep out of the sight and reach of children.

Store in the original packaging protected from light, from moisture and below 30°C.

## **Shelf-life**

Do not use after the expiry date stated on the carton after the inscription "exp".

## **Last update of the leaflet**

05/2020

Fercefol® is a trademark

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