SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE PHARMACEUTICAL PRODUCT

FERTAMIR 100 mg sachet with effervescent granule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Each sachet contains 307.69 mg iron III polymaltose complex (equivalent to 100 mg Fe^{+3})

Excipients:

Sodium bicarbonate……..….120 mg

Sodium carbonate anhidr…….....50 mg

Powdered sugar (Sucrose)….....1290 mg

For excipients see Section 6.1.

3. PHARMACEUTICAL FORM

Sachet contains granules for oral oral solution

The granules are brown

4. CLINICAL PROPERTIES

4.1. Therapeutic indications

Used in the treatment and prophylaxis of all iron deficiencies of different origin and iron deficiency anemia. Used in the treatment of iron supplements during pregnancy, lactation and childhood.

4.2. Posology and method of administration

Posology / administration frequency and duration:

It is used in children (≥ 12 years) and adults in doses equivalent to 100-200 mg of elemental

iron. Unless otherwise recommended by the doctor, 1 sachet should be used 1-2 times a day.

Duration of treatment

The duration of treatment depends on the state of iron metabolism (reduced intake, increased need, pathological loss) and the normalization of the number of erythrocytes. Achieving normal blood values in manifest iron deficiency is an average of 3-5 months of treatment. The treatment period for latent iron deficiency is 1-2 months.

Treatment should be continued to fill the body iron stores until the hemoglobin value reaches normal limits (usually 8-12 weeks), then at least 4 more weeks.

Route of administration

The sachet content is dissolved in a glass (200 ml) of water and mixed until it becomes a homogeneous mixture.

The prepared solution should be drunk immediately.

It can be used with or after meals.

It can be taken by mixing with fruit or vegetable juices.

Additional information on special populations:

Kidney / Liver failure:

FERTAMIR should not be used in severe liver and kidney diseases.

Pediatric population:

In children under 12 years of age, there is currently insufficient data to recommend a dosage regimen for routine use.

Geriatric population:

Practice in the elderly is just like in adults.

4.3. Contraindications

- Known to be hypersensitive to the active ingredient it contains or to any of the excipients in section 6.1.
- All anemia without iron deficiency (Ex: hemolytic anemia)
- Iron overload (hemochromatosis, chronic hemolysis)
- Hypersensitivity to iron, iron use disorder (lead anemia, sidero acrestic anemia)
- Thalassemia (Mediterranean anemia)
- Serious liver and kidney stones
- Regular continuous blood transfusions
- In patients with HIV infection, daily iron supplementation should not be performed unless iron-deficiency anemia is clinically confirmed.

4.4. Special use warnings and precautions

- Diseases that may be at the basis of iron deficiency or iron deficiency anemia should be identified and these diseases should be treated appropriately.

- Anemia should always be treated under the supervision of a doctor.

- If the treatment is not successful (after 3 weeks, the increase in hemoglobin level is not about 2-3 g / dl), it should be rearrange.

- Patients who have repeated blood transfusions should be warned against iron overload as iron is given with erythrocyte.

- It should be used with caution in cases with alcoholism and intestinal inflammation.

- Carefully given to patients with stomach ulcers.

- During the use of oral iron preparations, the color of the stool may darken, this is normal and does not require any measures. It does not cause an error during the search

for hidden blood in the stool. Therefore, there is no need to discontinue treatment during this examination.

- In anemia due to infection or malignancy, the iron taken is stored in the reticuloendothelial system and is used as mobilized following the treatment of primary disease.

- It should not be taken with milk.

- Accidental administration / ingestion of iron-containing products in children under 6 years of age causes fatal poisoning. Therefore, keep these medicines out of the reach of children. In case of overdose, patients should be warned to call a doctor or poison consultant.

This medicinal product contains 2.37 mmol (54.55 mg) sodium per dose. This should be considered for patients on a controlled sodium diet.

FERTAMIR contains sucrose as 1290 mg powdered sugar in each dose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency should not use this medicine because of the sugar it contains.

4.5. Interactions with other medicinal products and other forms of interactions

Parental administration of iron with FERTAMIR is not recommended on the grounds that it may reduce the absorption of FERTAMIR.

Milk and eggs reduce iron absorption. If it should be taken with tetracycline, cholestramine, antacids, penicillamine and oral gold compounds, it should be given few hours apart.

Salicylates with phenylbutasone and oxyphenbutazone, can cause irritation of the intestinal mucosa. The benzidine test for iron therapy can give a positive result.

It should not be used with tea, coffee and milk. It should be used with caution in those with bowel tumors.

The interactions that occur when bivalent iron-containing preparations are taken with foods and some drugs (tetracycline, etc.) are not expected with the trivalent iron-hydroxide polymaltose complex in the composition of FERTAMIR. However, since it may interact with calcium-containing preparations, a minimum of 2 hours must pass between the two.

Since the absorption of drugs containing levothyroxine is disrupted when taken together with FERTAMIR, two drugs should be taken at least 2 hours apart.

Vitamin C is known to increase iron absorption.

Additional information on special populations

There is no interaction study on special populations.

Pediatric population:

There are no interaction studies regarding the pediatric population.

4.6. Pregnancy and lactation

General advice:

Pregnancy category: A

Women with childbearing potential / Contraception

No negative effects on women with childbearing potential / birth control.

Pregnancy period

FERTAMIR can be used during pregnancy, after consultation with the physician.
It is used as an iron supplement during pregnancy.

Well-managed epidemiological studies do not show that FERTAMIR has adverse effects on pregnancy or the health of the fetus / newborn child.

Lactation period

Iron passes into breast milk. This transition does not change according to the current iron level of the mother and the amount of iron taken with food. For this reason, giving an iron preparation to the nursing mother does not cause an iron intoxication in the baby or the elimination of the iron deficiency in the baby. FERTAMIR can be used during the lactation period after consultation with the physician.

Reproductive ability / Fertility

It has no effect on reproductive ability.

4.7. Effects on the ability to drive and use machines

It does not have a negative effect on the use of tools and machines.

4.8. Undesirable effects

The undesirable effects stated are classified according to the following rule:

Very common (≥1 / 10), common (≥1 / 100 to <1/10); uncommon (≥1 / 1.000 to <1/100); rare (≥1 / 10,000 to <1 / 1,000); very rare (<1 / 10,000), unknown (cannot be estimated from the available data).

Immune system diseases

Very rare: Allergic reactions, asthma

Nervous system disorders

Uncommon: Headache

Gastrointestinal diseases

Very common: Change in stool color

Common: Diarrhea, nausea, dyspepsia

Uncommon: Vomiting, constipation, abdominal pain, tooth discoloration

Skin and subcutaneous tissue disorders

Uncommon: urticaria, skin rash, exanthema, itching.

Very rare: Localized skin reactions

Kidney and urinary disorders

Rare: change in urine color

4.9. Overdose and treatment

Acute iron poisoning is not common in adults. It is more common in young children. Overdose of more than 20 mg per kilogram poses a potential risk. Taking a total of 0.5 g of iron in young children can cause life-threatening situations, and after 1-2 g, it may result in death.

It is possible to see four characteristic phases in poisoning. Nausea, vomiting, diarrhea are seen in the first 6 hours after ingestion. Hypotension, shock, acidosis, convulsion may be seen in high doses (doses exceeding 20 mg / kg). In the second phase, an improvement in mild cases follows. In the third phase (after 12-18 hours) liver damage, tubular necrosis, cardiovascular shock, coagulapathy are possible symptoms. In the fourth phase (within 2-6 weeks) esophagus, stomach and duodenum stenosis occurs.

Treatment :

If a high dose is taken the stomach is washed or if the stomach cannot be washed, the patient must be vomited. As a further measure, the intestines can be washed. In the presence of serum iron concentration 3.5-5 mg / L (63-85 mmol) and strong clinical manifestations of iron

poisoning, excretion of the chelate compound (Desferroxamine) from the kidney is stimulated. Desferroxamine is given intravenously at 15 mg / kg / h; maximum 80 mg / kg / 24 hours. Chelating agents such as sodium-EDTA can also be used. In case of shock, patient be supported by i.v perfusion.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Trivalent Oral Iron Preparations
ATC code: B03AB05

Iron is found in all cells in the body and has vital functions. Ionic iron is present in the structure of enzymes (cytochrome oxidase, xanthine oxidase, succinic dehydrogenase, etc.) that play a role in energy transfer. In the case of iron deficiency, deficiencies of these vital functions arise. With the application of the iron III hydroxide polymaltose complex, the iron production and the resulting effects are eliminated in anemias caused by iron deficiency by means of iron III ion.

5.2. Pharmacokinetic properties

General properties

Absorption:

It is rapidly absorbed from the gastrointestinal tract after taking FERTAMIR orally. The amount of iron absorbed depends on the iron deficiency of the person being treated. The greater the iron deficiency, the greater the absorption.

Distribution:

Iron binds 90% of plasma proteins and hemoglobin.
The absorbed iron is used in the synthesis of hemoglobin and myoglobin or transported to iron stores. In this way, iron deficiency symptoms disappear.

Biotransformation:

Iron is kept in a dynamic balance in plasma. When creating a new transferrin-iron complex with iron from the intestine, most (about 80%) iron carried in plasma with transferrin is transferred to precursor cells and hepatic reticuloendothelial cells in the bone marrow. The iron-transferrin complex enters the cell with receptor-mediated endocytosis, is enclosed in a non-lysosomal acidic vesicle and is removed from the iron complex, the remaining apotransferrin-receptor complex returns to the membrane and is used here. Iron is transferred to mitochondria, added to protoporphyrin and transformed immediately in erythroid cells, or combined with ferritin and stored. In iron deficiency, the number of receptors increases.

Elimination:

Iron that is not absorbed from the gastrointestinal tract is excreted through the faeces.
Only 1 mg of iron is eliminated per day through bile and urine. Women also lose iron through menstruation. The plasma half-life is 1.5 hours.

Linearity / Nonlinear State:

Its pharmacokinetics are linear. Plasma levels increase depending on the doses given.

5.3. Preclinical safety data

Non-clinical data does not indicate a particular hazard to humans based on traditional safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and reproductive toxicity studies.

In animal studies with white mice and rats, LD50 value for the Iron III Hydroxide Polymaltose complex could not be determined at the dose of iron administered orally up to 2000 mg per kilogram of body weight.

6. PHARMACEUTICAL PROPERTIES

6.1. Excipients List

Sodium bicarbonate

Sodium carbonate anhydrous

Mannitol E 421

Powdered sugar (sucrose)

Citric acid, anhydrous F3500

Tartaric acid

Povidon K-30 (PVP-30)

Cherry Flavor

Sucralose

6.2. Incompatibility

There is no evidence that FERTAMIR is incompatible with any drug or substance..

6.3. Shelf life

24 months.

6.4. Special warnings for storage

Store at room temperature below 25ºC. Drink the prepared solution immediately, do not save it.

6.5. The nature and content of the packaging

20 and 30 single-dose sachets (PET / Al / PE foil) containing 307.69 mg iron III polymaltose complex.

6.6. Disposal of remaining medicinal products and other special precautions

Kullanılmamış olan ürünler ya da atık materyaller ‘Tıbbi Atıkların Kontrolü Yönetmeliği’ ve ‘Ambalaj ve Ambalaj Atıklarının Kontrolü Yönetmelikleri’ ne uygun olarak imha edilmelidir.

7. MARKETING AUTHORIZATION HOLDER

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8. REGISTRATION CERTIFICATE NUMBER

2018/171

9. FIRST REGISTRATION DATE/RENEWAL OF REGISTRATION

First registration date: 29.03.2018
Date of renewal registration:

10. DATE OF RENEWAL SPC

02/05/2019