

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription

Tardyferon® 80 mg Tablets

Active ingredients – Each film-coated tablet contains:

Ferrous iron 80 mg (as Ferrous sulfate dried 247.25 mg)

Inactive and allergenic ingredients in the preparation: see section 6 "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

Take the preparation according to the instructions in section 3 "How should you use the medicine?". Consult a pharmacist if you need more information. Refer to a doctor if the symptoms of the illness worsen or do not improve.

1. WHAT IS THE MEDICINE INTENDED FOR?

Prevention and treatment of iron deficiency anemia.

Therapeutic group: Iron preparations for the treatment of anemia.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient, or to any of the additional ingredients contained in the medicine (list of inactive ingredients in section 6 "Further information").
- you suffer from iron overload in conditions such as hemochromatosis, thalassemia, refractory anemia or bone marrow failure.

Special warnings regarding use of this medicine

Before starting treatment with Tardyferon, tell the doctor or pharmacist if:

- Consult a doctor or pharmacist before taking Tardyferon.
- If you are taking Tardyferon due to iron deficiency, the cause of the iron deficiency should be investigated.
- If the iron deficiency is associated with an inflammatory disease, treatment with Tardyferon will not be effective.
- Due to risk of mouth ulcers and discoloration of the teeth, tablets should not be sucked, chewed or kept in the mouth. Swallow the tablet whole with water. If you are unable to follow these instructions or experience difficulties swallowing, consult your doctor.
- You have difficulty swallowing.
- You accidentally choked on a tablet; refer to a doctor immediately. If the tablet got into your airways, there is a risk of ulceration and narrowing of the airways. This may cause a persistent cough, coughing up blood and/or a feeling of shortness of breath, even if the inhalation occurred several days or months prior to the onset of symptoms. You should get checked urgently to make sure that the inhaled tablet has not damaged your airways.
- According to the literature, coloration of the walls of the gastrointestinal tract has been observed in elderly patients who suffer from chronic kidney disease, diabetes and/or hypertension and who are taking medicines for these illnesses as well as iron supplement for the treatment of anemia.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutrition supplements, tell the doctor or pharmacist: If you are already being treated with the following medicines, do not take Tardyferon, unless recommended by your doctor. Some medicines cannot be taken at the same time, while others require certain adjustments (e.g., separate ingestion times).

- If you are taking injectable medicines containing iron, you should avoid taking Tardyferon.
- Tell your doctor if you are taking medicines containing acetyldihydroxamic acid.
- Wait at least two hours between taking Tardyferon and taking the following medicines:
 - antibiotics from certain groups (cyclins or fluoroquinolones)
 - medicines to treat bone fragility (bisphosphonates)
 - medicines to treat joint diseases (penicillamine)
 - preparations to treat high levels of acidity in the stomach: gastrointestinal mineral preparations or antacids (aluminum, calcium and magnesium salts)
 - medicines to treat thyroid disease (thyroxine)
 - medicines to treat Parkinson's disease (entacapone, methyl dopa, levodopa)
 - medicines or products containing zinc, calcium or strontium

Use of the medicine and food

It is preferable to take the medicine before or with a meal, depending on the gastrointestinal tolerance.

Pregnancy and breastfeeding

This medicine can be used during pregnancy, if necessary, as recommended by a doctor.

Can be used during breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult your doctor or a pharmacist before taking the medicine.

Driving and operating machinery

It is unlikely that the use of Tardyferon will affect the ability to drive or operate machinery.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The recommended dosage, unless otherwise instructed by your doctor, is usually:

For the treatment of anemia due to iron deficiency in adults: usually 1 tablet per day.

For the prevention of anemia due to iron deficiency in pregnant women: usually 1 tablet per day or 1 tablet every two days during the last two trimesters of pregnancy (i.e., from the fourth month and on), according to the doctor's discretion. Use this medicine only for the period determined by the attending doctor.

Do not exceed the recommended dosage.

Method of administration

Swallow the tablet whole with a full glass of water.

Crushing/halving/chewing: Do not suck, chew or keep the tablet in your mouth.

Do not crush/halve/chew the tablet due to the risk of mouth ulcers and discoloration of the teeth.

If you accidentally take a higher dosage

The symptoms of overdose of iron include the following signs:

- severe gastrointestinal irritation which can lead to necrosis of the gastrointestinal tissue (necrosis of the mucosa of the gastrointestinal system). The main

symptoms are: abdominal pains, nausea, vomiting (sometimes with blood) and diarrhea (sometimes with black stools).

- This can be accompanied by metabolic acidosis and shock. The main symptoms are: rapid breathing or shortness of breath, increased heart rate, headache, confusion, drowsiness, fatigue, loss of appetite, abdominal pain, vomiting, and rapid drop in blood pressure which can progress to loss of consciousness with convulsions (convulsive coma).
- Signs of reduced kidney function (significantly reduced volume of urine) and liver (upper right abdominal pains, yellowing of the skin or eyes and dark urine).

Long-term effects in the gastrointestinal system can occur with narrowing of the gastrointestinal tract (stenosis of the gastrointestinal tract), which can manifest by nausea, swelling, constipation and abdominal bloating.

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the scheduled time, take it as soon as you remember. However, if it is almost time for the next dose, do not take the forgotten dose; take only the next dose at the usual time. Do not take a double dose to compensate for the forgotten dose.

If you stop taking the medicine

Adhere to the treatment regimen recommended by the doctor. Discontinuation of the treatment may cause problems.

Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the doctor.

If you have further questions, refer to the doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Tardyferon may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Common side effects – occur in 1-10 users in 100

- constipation
- diarrhea
- abdominal bloating
- abdominal pain
- coloration of the stools
- nausea

Uncommon side effects – occur in 1-10 users in 1,000

- swelling in the throat (laryngeal edema)
- abnormal stools
- discomfort and pain in the upper abdomen (dyspepsia (digestion difficulties))
- vomiting
- severe stomach inflammation (gastritis)
- itching
- appearance of rash and skin redness

Side effects of unknown frequency (effects whose frequencies have not been determined)

- allergic reaction (hypersensitivity)
- onset of a rash accompanied with itching [urticaria (hives)]
- discoloration of the teeth**
- mouth ulcers**
- esophageal lesions*
- necrosis of lung tissue (pulmonary necrosis)*

- inflammation of the lung (pulmonary granuloma)*
- narrowing of the airways (bronchial stenosis)*
- throat ulcers*
- esophageal ulcers*
- discoloration of the walls of the gastrointestinal tract***

* All patients, but especially elderly patients and patients with difficulty swallowing, may be at risk of ulceration of the throat or esophagus (the tube that connects the mouth to the stomach). If the tablet enters the airways, there is risk of ulceration of the bronchi (the main air passageways in the lungs), which may lead to narrowing of the bronchi.

** Due to incorrect administration, when the tablets are chewed, sucked or kept in the mouth.

*** According to the literature, coloration of the walls of the gastrointestinal tract has been observed in elderly patients who suffer from chronic kidney disease, diabetes and/or hypertension and who are receiving medications for these illnesses as well as iron supplementation for the treatment of anemia.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report side effects of drug treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

In addition, they can be reported to Padagis through the following address:

Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package and tray (blister). The expiry date refers to the last day of that month.
- Store below 30°C.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Cellulose microcrystalline, maltodextrin, sepifilm LP010, ammonio methacrylate copolymer type B, glycerol dibehenate, talc, ammonio methacrylate copolymer type A, triethylcitrate, titanium dioxide, red iron oxide, yellow iron oxide.

What the medicine looks like and contents of the package:

Round, pink-orangish, film-coated tablets.
30 film-coated tablets in a pack.

Registration Holder and Importer: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.

Revised in March 2023 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 13566.31400

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