Patient Package Insert
According to Pharmacists' Regulations (Preparations) – 1986
This medicine can be sold without a physician's prescription

Tardyferon Tablets 80 mg

Active ingredients - each tablet contains:
Ferrous sulfate dried 247.25 mg (equivalent to approximately 80 mg ferrous iron).

Inactive ingredients and allergens in the preparation: see section 6 "**Additional information**".

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.
Take the preparation according to the instructions in the dosage section of this leaflet. Consult a pharmacist if you need more information. Refer to a doctor if the signs of illness (symptoms) worsen or do not improve.

1. What is the medicine intended for?
For the treatment and prevention 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 hypersensitive (allergic) to the active ingredient or to any of the other ingredients that the medicine contains.
- you suffer from iron overload in conditions such as hemochromatosis, thalassemia, refractory anemia or bone marrow suppression.

Special warnings regarding the use of this medicine
Before starting treatment with Tardyferon, tell the doctor if:
- you have difficulty swallowing.
- you accidentally choked on a tablet; refer to a doctor immediately. If the tablet gets 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 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.

Warnings:
- Consult a doctor or pharmacist before taking Tardyferon.
- If you are taking Tardyferon due to iron deficiency, the cause of this iron deficiency should be investigated.
- Reduced iron levels associated with inflammatory syndromes do not respond to treatment with Tardyferon tablets.
- Due to the 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 a full glass of water. If you are unable to follow these instructions or experience difficulties swallowing, consult your doctor.
- 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 to iron for the treatment of anemia.

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 medications, 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 drugs containing iron, you should avoid taking Tardyferon.
- Tell your doctor if you are taking medicines containing acetohydroxamic 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)
  - Antacids: gastrointestinal mineral preparations or antacids (aluminum, calcium and magnesium salts)
  - Medicines to treat a thyroid disease (thyroxine)
  - Medicines to treat Parkinson's (entacapone, methyldopa, levodopa)
  - Medicines or products containing zinc, calcium or strontium

Use of this medicine and food
Take this medicine with a full glass of water, preferably before or with a meal, depending on the gastrointestinal tolerance.

Pregnancy, breastfeeding and fertility
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.
Fertility: Animal studies do not indicate any effect on fertility in women and in men.

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

3. How should you use this medicine?
Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. The recommended dosage, unless otherwise instructed by your doctor:
For the treatment of iron deficiency in adults: usually 1 tablet daily.
For the prevention of iron deficiency in pregnant women: 1 tablet per day or every two days during the last two trimesters of pregnancy (from the fourth month), according to the doctor's discretion. Use this medicine only for the period determined by the attending doctor.
Do not exceed the recommended dose.

How to take
The tablet should be swallowed whole. 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.
Take with a full glass of water, preferably before or during a meal, depending on your gastrointestinal system tolerance.

If you have accidentally taken a higher dosage
Cases of overdose with iron salts have been reported, particularly in children following massive ingestion. The symptoms of overdose include the following signs:
- Gastrointestinal irritation with nausea, vomiting (sometimes blood) and diarrhea (sometimes with black stools).
- Cardiovascular shock (circulatory system) and metabolic acidosis (rapid breathing or shortness of breath, increased heart rate, headache, convulsions, confusion, drowsiness, fatigue, loss of appetite, stomach ache, vomiting).
- Signs of kidney failure (significantly reduced volume of urine) and liver failure (upper right abdominal pain, yellowing of the skin or eyes and dark urine).

If you have taken an overdose or if a child or someone else 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 this medicine at the designated time, take a dose as soon as you remember. However, if it is almost time for the next dose, take the next dose at the usual set time. Do not take a double dose to make up for the forgotten dose.

If you stop taking this medicine
Adhere to treatment regimen as 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 this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
If you have further questions regarding the use of this medicine, consult the doctor or pharmacist.

4. Side effects
As with any medicine, the use of Tardyferon may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.
Serious side effects - Stop using Tardyferon and refer to a doctor as soon as possible if they occur:
- Severe abdominal pain
- Vomiting (uncommon side effects)
- Allergic reaction (hypersensitivity) (side effects whose frequency is unknown)
- Swelling of the throat (laryngeal edema) (uncommon side effects)
- Pulmonary tissue necrosis (pulmonary necrosis)* (side effects whose frequency has not yet been determined)
- Pneumonia (pulmonary granuloma)* (side effects whose frequency has not yet been determined)
- Narrowing of the airways (bronchial stenosis)* (side effects whose frequency has not yet been determined)

Common side effects - appear in 1-10 out of 100 users
- Constipation
- Diarrhea
- abdominal bloating
- Abdominal pain
- Abnormal coloration of the stools
- Nausea

Uncommon side effects - appear in 1-10 out of 1,000 users
- Abnormal stools
- Discomfort and pain in the upper abdomen (dyspepsia)
- Vomiting
- Stomach inflammation (gastritis)
- Itching
- Appearance of rash and skin redness

Side effects with unknown frequency (effects whose frequency has not been determined yet)
- Discoloration of the teeth*, **
- Oral lesions (mouth ulcers)**
- Esophageal lesions*
- Appearance of rash and skin redness accompanied by itching (hives)
- 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 throat or esophageal ulceration (the tube that connects the mouth to the stomach). If the tablet enters the airways, there is a risk of bronchial ulceration (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 any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse effects reporting, or via the following link: https://sideeffects.health.gov.il
Additionally, side effects can be reported to Perrigo via the following address: www.perrigo-pharma.co.il

5. How should the medicine be stored?
- Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, 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 blister. The expiry date refers to the last day of that month.
- Store below 30°C.

6. Additional information
In addition to the active ingredient, the medicine also contains:
Tablet contents:
Cellulose microcrystalline, maltodextrin, ammonio methacrylate copolymer type B, glycerol dibehenate, talc, ammonio methacrylate copolymer type A, triethylcitrate.
Coating composition:
Sepifilm LP010, titanium dioxide, triethylcitrate, red iron oxide, yellow iron oxide.

What the medicine looks like and contents of the package:
Round orangish-pink colored coated tablet.

Registration Holder: Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham.

Manufacturer: Pierre Fabre Medicament Production, Boulogne, France.

Revised in September 2020.

Drug registration number at the National Medicines Registry of the Ministry of Health:
13566.31400

Tardyferon PIL PB1220-07

22.9.20