PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed without 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**" and section 2 "**Important information about some of the ingredients in this medicine**".

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 (for further information please see section 6 "**Further information**").
- you have more iron in your body than you need.
- you have anemia (insufficient quantity of red blood cells) not linked to iron deficiency or causing iron overload (such as thalassemia, refractory anemia or aplastic anemia).

Special warnings regarding use of this medicine
Before starting treatment with Tardyferon, tell the doctor or pharmacist if:
- If you are taking Tardyferon due to iron deficiency, the cause of the iron deficiency should be investigated so that it can be treated.
- If the iron deficiency is associated with an inflammatory disease, the 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.
- According to the literature, rare cases of discoloration of the walls of the stomach and digestive tract (melanosis) have been reported in elderly patients suffering from kidney disease, diabetes and/or hypertension and who are taking medicines for these diseases and iron supplementation to treat their anemia. This melanosis may hinder gastrointestinal surgery and must therefore be taken into consideration, especially if surgery is scheduled. In view of this risk, it is advisable to notify the surgeon of ongoing iron supplementation (see section 4 "**Side effects**").

During or after your treatment, talk to your doctor or pharmacist immediately:
- If the medicine is inadvertently aspirated (goes down the "wrong way"), it can enter your airways. If the medicine comes into contact with the respiratory tract, this can result in injuries such as necrosis (death of tissue) or inflammation of the bronchi (areas where air passes through the lungs) or the esophagus (the tube connecting the mouth to the stomach). These injuries can cause narrowing of the bronchi. This can result in a persistent cough, coughing up blood, and/or feelings of breathlessness, even if aspiration happened several days or months before these symptoms occur.
- If the medicine has entered the airways and you have one or more of these signs, contact your doctor or nearest emergency unit as soon as possible for a specialist evaluation, to make sure that there is no injury to the respiratory tract.

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.
- Wait at least two hours between taking Tardyferon and taking the following medicines:
  - antibiotics from certain groups (cyclins or fluoroquinolones)
  - medicines to treat HIV/AIDS (integrase inhibitors, bictegravir)
  - medicines to treat bone fragility (bisphosphonates)
  - medicines to treat joint diseases, Wilson's disease or to prevent kidney stones (penicillamine, trientine)
  - 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, methyldopa, levodopa)
  - medicines or products containing zinc, calcium or strontium
  - medicines to treat a chronic urinary infection (acetohydroxamic acid).

Use of the medicine and food
It is preferable to take the medicine before or with a meal, depending on the gastrointestinal tolerance.
You should not drink large quantities of tea, coffee or red wine because this can decrease the absorption of iron in your body.
It is not advisable to take this medicine at the same time as whole grains (fibers, legumes, oil seeds), some proteins (eggs), or foods or drinks containing calcium (cheese, milk, etc.). Leave an interval of at least 2 hours between taking iron salts and these foods.

Pregnancy and 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.
The data available on iron intake during the first trimester of pregnancy are limited, but there are a large number of bibliographic data available on women during the second and third trimester of pregnancy. These data do not show evidence of risk of malformation or toxicity for the fetus and/or newborn. Consequently, Tardyferon can be used during pregnancy if needed.
This medicine can be used by breastfeeding women.

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

Important information about some of the ingredients in this medicine
Tardyferon contains less than 1 mmol sodium (23 mg) per tablet, i.e., it is essentially sodium-free.

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 onwards), 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 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.
To be taken with a full glass of water, preferably before meals or during meals (except with certain foods listed in "**Use of the medicine and food**" section) depending on gastrointestinal tolerance.

If you accidentally take a higher dosage
The symptoms of overdose of iron include the following signs:
- An intense 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 poorly functioning kidneys (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 be characterized by nausea, bloating, constipation and abdominal distension.

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
Problems may occur after treatment is stopped.
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 distension)
- abdominal pain
- abnormal colouration of the stools
- nausea

Uncommon side effects – occur in 1-10 users in 1,000
- swelling in the throat (laryngeal edema)
- abnormal stools
- indigestion (dyspepsia)
- vomiting
- inflammation of the stomach lining (gastritis)
- itching
- sudden appearance of skin redness (erythematous rash)

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 (dental dyschromia)**
- mouth ulcers**
- esophageal lesions (esophageal injury/ulceration)*
- necrosis of pulmonary cells or tissue (pulmonary necrosis)*
- inflammation of the lung tissue (pulmonary granuloma)*
- narrowing of the airways (bronchostenosis)*
- throat ulcers (pharyngeal ulceration)*
- esophageal ulcers*
- discoloration of the wall of the stomach and the intestinal tract (gastrointestinal melanosis) (see section 2)
- chronic inflammation of the stomach lining (erosive gastritis)
- deep wound in the stomach lining (gastric ulcer)
- bleeding from a deep wound in the stomach wall (hemorrhagic gastric ulcer)

* 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.

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 closed 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:
Core: Cellulose microcrystalline, maltodextrin, ammonio methacrylate copolymer type B, glycerol dibehenate, talc, ammonio methacrylate copolymer type A, triethylcitrate.
Film coating: Sepifilm LP010, titanium dioxide, triethylcitrate, red iron oxide, yellow iron oxide.

What the medicine looks like and contents of the package:
Round, pink-orangish, film-coated tablet.
30 film-coated tablets in a pack.

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

Revised in April 2024.

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

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