Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
The medicine is dispensed with a doctor's prescription only

Deferasirox Teva 125 mg
Deferasirox Teva 250 mg
Deferasirox Teva 500 mg

Dispersible tablets
Each dispersible tablet contains:
Deferasirox 125 mg
Deferasirox 250 mg
Deferasirox 500 mg

For information on inactive ingredients and allergens: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, contact the doctor or pharmacist.
This medicine has been prescribed for the treatment of your illness or for the treatment of your child's illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is the medicine intended for?

- For treatment of chronic iron overload caused by blood transfusions (transfusional hemosiderosis) in adult and pediatric patients (aged 2 years and older).
- For treatment of chronic iron overload in patients with non-transfusion dependent thalassemia syndromes aged 10 years and older.

Therapeutic group: iron chelating agents
Repeated blood transfusions are sometimes necessary in patients suffering from certain types of anemia, such as thalassemia, sickle-cell disease and myelodysplastic syndrome [MDS]. However, repeated blood transfusions may cause a build-up of excess iron. This is because blood contains iron, and the body does not have a natural way to remove the excess iron received with the blood transfusions.
In patients with non-transfusion-dependent thalassemia, iron overload may develop over time, mainly due to increased absorption of dietary iron in response to low blood cell counts. Over time, the excess iron can damage vital organs, such as the liver and heart.
Iron chelator medicines are used to remove the excess iron and reduce the risk of damage to the body's organs.
Deferasirox Teva traps and removes excess iron, which is then excreted mainly in the stool.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to deferasirox or any of the additional ingredients contained in the medicine, that appear in section 6 "Further information". If this applies to you, **tell the doctor before taking Deferasirox Teva.** If you think you are allergic, consult the doctor.
- You have a moderate or severe kidney disease.
- You are currently taking another iron chelator medicine.

Deferasirox Teva is not recommended if
- You are at an advanced stage of myelodysplastic syndrome (MDS: decreased production of blood cells by the bone marrow) or have advanced cancer.

Special warnings regarding use of the medicine
Before treatment with Deferasirox Teva, tell the doctor if:
- You have a liver or kidney problem.
- You have a cardiac problem caused by iron overload.
- You notice a marked decrease in urine output (sign of a kidney problem).
- You have a severe rash or breathing difficulties and dizziness or swelling, mainly of the face and throat (signs of a severe allergic reaction, also see section 4 "Side effects").
- You have a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms, enlarged lymph nodes (signs of a severe skin reaction, also see section 4 "Side effects").
- You experience a combination of drowsiness, upper right abdominal pain, yellowing or increased yellowing of the skin or eyes and dark urine (signs of liver problems).
- You experience difficulty thinking, remembering information or solving problems, feel less alert or aware of your surroundings or feel very sleepy with low energy (signs of a high level of ammonia in the blood, which may be associated with liver or kidney problems, also see section 4 "Side effects").
- You vomit blood and/or have black stool.
- You frequently have abdominal pain, particularly after eating or taking Deferasirox Teva.
- You have frequent heartburns.
- You have a low platelet or white blood cell count in blood tests.
- You have blurred vision.
- You have diarrhea or vomiting.

If any of these conditions apply to you, tell the doctor immediately.

Elderly population (aged 65 years and over)
Elderly people aged 65 years and over can use the same dose of Deferasirox Teva as other adults. Elderly patients may experience more side effects (primarily diarrhea) than younger patients. They should be monitored closely by their doctor for detection of side effects that may require dosage adjustment.

Children and adolescents
Deferasirox Teva can be used in children and adolescents from the age of 2 years and above to treat chronic iron overload caused by blood transfusions, and from the age of 10 years and above to treat non-transfusion-dependent chronic iron overload in thalassemia patients. The doctor will adjust the dosage according to the child's growth.
Deferasirox Teva is not indicated for use in children under 2 years of age.

Tests and follow-up
- During the course of treatment, you will need to undergo regular blood and urine tests. These tests will monitor the amount of iron in your body (blood ferritin levels) to check whether Deferasirox Teva is working properly.
- The tests will also monitor kidney function (creatinine levels, presence of protein in the urine) and liver function (levels of transaminases, bilirubin and alkaline phosphatase in the blood). Your doctor may ask you to undergo a kidney biopsy, if he suspects significant kidney damage.
- You may also undergo MRI (magnetic resonance imaging) tests to determine the amount of iron in the liver. The doctor will take these tests into consideration when deciding which dosage of deferasirox is most suitable for you, and will also use these tests to decide when you should stop taking Deferasirox Teva.
- You must undergo hearing and vision tests before beginning treatment and once a year during the course of treatment as a precautionary measure.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.
Deferasirox Teva must not be combined with other iron chelating preparations.
Do not take antacids (medicines used to treat heartburn) containing aluminium at the same time of day as Deferasirox Teva.
In particular, inform the doctor or pharmacist if you are taking:
- ciclosporin (used to prevent rejection of a transplanted organ or for other conditions, such as rheumatoid arthritis or skin asthma)
- simvastatin (used to lower cholesterol)
- certain painkillers or anti-inflammatory medicines (e.g. aspirin, ibuprofen, corticosteroids)
- oral bisphosphonates (used to treat osteoporosis)
- anticoagulant medicines (used to prevent or treat formation of blood clots)
- hormonal contraception (birth control preparations)
- bepridil, ergotamine (used to treat heart problems and migraines)
- repaglinide (used to treat diabetes)
- rifampicin (used to treat tuberculosis)
- phenytoin, phenobarbital, carbamazepine (used to treat epilepsy)
- ritonavir (used to treat HIV infection)
- paclitaxel (used to treat cancer)
- theophylline (used to treat respiratory diseases such as asthma)
- clozapine (used to treat psychiatric disorders such as schizophrenia)
- tizanidine (used as a muscle relaxant)
- cholestyramine (used to lower cholesterol levels in the blood)
- busulfan (used as a treatment prior to transplantation in order to destroy the original bone marrow before the transplantation).
- midazolam (used to ease anxiety and/or sleeping difficulties)

Additional tests may be required to monitor the levels of some of these medicines in your blood.

Use of the medicine and food
- Take Deferasirox Teva on an empty stomach and wait at least 30 minutes before eating any food, preferably at the same time each day.
- Dissolve the tablets in a glass of water, apple juice or orange juice.
- Do not dissolve the tablets in fizzy drinks or milk (also see below "How to take Deferasirox Teva").

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult the doctor before using the medicine. Deferasirox Teva is not recommended during pregnancy, unless clearly necessary. If you are using a hormonal contraceptive to prevent pregnancy, you should use an additional or different type of contraception (e.g., a condom), as Deferasirox Teva may reduce the effectiveness of hormonal contraceptives.
Breastfeeding is not recommended during treatment with Deferasirox Teva.

Driving and using machinery
If you feel dizzy after taking Deferasirox Teva, do not drive a vehicle or operate any tools or machinery until you feel normal again. Children should be cautioned against riding a bicycle or playing near the road, and the like.

Important information about some of the ingredients of the medicine
Lactose:
Deferasirox Teva tablets contain lactose (milk sugar). If you have an intolerance to certain sugars, inform the doctor before taking Deferasirox Teva.
- Each Deferasirox Teva 125 mg dispersible tablet contains approximately 85 mg lactose monohydrate.
- Each Deferasirox Teva 250 mg dispersible tablet contains approximately 170 mg lactose monohydrate.
- Each Deferasirox Teva 500 mg dispersible tablet contains approximately 341 mg lactose monohydrate.

Sodium:
The medicine contains less than 1 mmol (23 mg) sodium per tablet, and is therefore essentially considered 'sodium-free'.

3. How should you use the medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose and how you should take this medicine.
Treatment with Deferasirox Teva will be overseen by a doctor who is experienced in the treatment of iron overload.

Usual dosage:
Only your doctor will determine your dose and how you should take this medicine. In all patients, the dosage of Deferasirox Teva is related to the body weight. The doctor will calculate the dosage you need and tell you how many tablets to take each day.
The usual daily dosage at the start of the treatment is generally:
- For patients regularly receiving blood transfusions - 20 mg per kilogram body weight. A higher or lower starting dosage may be recommended by the doctor based on your individual treatment needs.
- For patients who do not regularly receive blood transfusions - 10 mg per kilogram body weight.

Depending on your response to treatment, the doctor may later adjust your treatment to a higher or lower dose.

The maximum daily dosage is:
- 40 mg per kilogram body weight for patients regularly receiving blood transfusions.
- 20 mg per kilogram body weight for adult patients not regularly receiving blood transfusions.
- 10 mg per kilogram body weight for children up to the age of 18 years not regularly receiving blood transfusions.

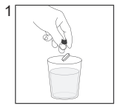
Do not exceed the recommended dose.

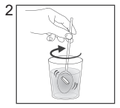
Duration of treatment:
Continue taking Deferasirox Teva every day, for as long as your doctor instructs you to. This is a long-term treatment, possibly lasting for months or years. The doctor will regularly monitor your condition to make sure that the treatment is having the desired effect (see also section 2: "Tests and follow-up").
If you have questions regarding the duration of treatment, contact to the doctor.

Method of administration:
When to take Deferasirox Teva?
- Take Deferasirox Teva once a day, every day, at about the same time.
- Take the tablets on an empty stomach and wait at least 30 minutes before eating any food.

Taking Deferasirox Teva at the same time each day will help you remember when to take the tablets.

How to take Deferasirox Teva?

1 
Place the tablet(s) into a glass of water, apple or orange juice (100-200 ml).

2 
Stir until the tablet(s) dissolve(s) completely. The liquid in the glass will look cloudy.

3 
Drink all the contents of the glass, then add a little water or juice to what remains in the glass, stir and drink that as well.

Do not dissolve the tablets in fizzy drinks or milk.
Do not chew, break or crush the tablets, do not swallow the tablets whole.
For any question about how Deferasirox Teva works or why it has been prescribed for you, consult your doctor or pharmacist.

If you have taken an overdose, or if a child or someone else has accidentally swallowed some medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the medicine package with you. Urgent medical treatment may be necessary.
You may experience effects such as abdominal pain, diarrhea, nausea and vomiting, and kidney or liver problems that could be serious.

If you forget to take the medicine:
If you forgot to take the medicine at the required time, take the dose as soon as you remember on the same day. Take the next dose at the usual time. Do not take a double dose on the following day to compensate for the forgotten tablet(s).
Adhere to the treatment as recommended by the doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking the medicine:
Do not stop treatment with Deferasirox Teva without explicit instruction from the doctor. If you stop taking Deferasirox Teva, the excess iron will no longer be removed from your body (also see above "Duration of treatment").

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

4. Side effects

Like with all medicines, using Deferasirox Teva may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.
Most of the side effects are mild to moderate and will generally pass after a few days to a few weeks of treatment.

Some side effects could be severe and require immediate medical treatment.
These side effects are uncommon (may affect up to 1 in every 100 patients) or rare (may affect up to 1 in every 1,000 patients).

Stop taking the medicine and contact a doctor immediately if any of the following cases applies to you or your child:
- severe rash, or breathing difficulties and dizziness or swelling, mainly of the face and throat (signs of severe allergic reaction)
- a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms, enlarged lymph nodes (signs of severe skin reaction)
- a marked decrease in urine output (sign of a kidney problem)
- a combination of drowsiness, upper right abdominal pain, yellowing or increased yellowing of the skin or eyes and dark urine (signs of liver problems)
- difficulty thinking, remembering information, or solving problems, reduced alertness or awareness or feeling very sleepy with low energy (signs of a high level of ammonia in the blood, which may be associated with liver or renal problems and lead to a change in the brain function)
- bloody vomit and/or black stool
- frequent abdominal pains, particularly after eating or taking Deferasirox Teva
- frequent heartburns
- partial loss of vision
- severe upper abdominal pain (pancreatitis).

Some side effects could become serious.
These side effects are uncommon.

Contact a doctor as soon as possible if:
- you suffer from blurred or cloudy eyesight
- you suffer from reduced hearing

Additional side effects:
Very common side effects (may affect more than 1 in every 10 patients):
- abnormal tests related to kidney function

Common side effects (may affect up to 1 in every 10 patients):
- gastrointestinal disorders, such as nausea, vomiting, diarrhea, abdominal pain, bloating, constipation, indigestion
- rash
- headache
- abnormal tests related to liver function
- itching
- abnormal urine tests (protein in the urine)

If any of the above effects affects you severely, contact a doctor.

Uncommon side effects (may affect up to 1 in every 100 patients):
- dizziness
- fever
- sore throat
- swelling of arms or legs
- change in the color of the skin
- anxiety
- sleep disorders
- tiredness

If any of the above effects affects you severely, contact a doctor.

Side effects of unknown frequency (frequency cannot be estimated from the available data):
- a decrease in the number of blood cells involved in blood clotting (thrombocytopenia), in the number of red blood cells (severe anemia), in the number of white blood cells (neutropenia) or in the number of all types of blood cells (pancytopenia)
- hair loss
- kidney stones
- low urine output
- a tear in the stomach or intestinal wall that may cause pain and nausea
- severe upper abdominal pain (pancreatitis)
- abnormal level of acid in the blood

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

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. The expiry date refers to the last day of that month.
- **Store below 25°C.**
- Do not use a package that is damaged or shows signs of tampering.
- Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Further information

In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, crospovidone, microcrystalline cellulose (avicel PH 113), microcrystalline cellulose (avicel PH 112), povidone, magnesium stearate, sodium lauryl sulfate, colloidal silicon dioxide.

What the medicine looks like and the contents of the package:
Deferasirox Teva is supplied as dispersible tablets in a pack containing 30 tablets.
- Deferasirox Teva 125 mg: a white - beige, round and flat tablet, embossed with the number "77" on one side and with the number "438" on the other side.
- Deferasirox Teva 250 mg: a white - beige, round and flat tablet, embossed with the number "77" on one side and with the number "439" on the other side.
- Deferasirox Teva 500 mg: a white - beige, round and flat tablet, embossed with the number "77" on one side and with the number "440" on the other side.

Manufacturer's and License holder's name and address:
Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in June 2022 according to MOH guidelines

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health: 161-12-34651, 161-13-34650, 161-14-34653