The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it in December 2018
PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Deferasirox Teva 125 mg
Dispersible tablets
Each dispersible tablet contains:
Deferasirox 125 mg

Deferasirox Teva 250mg
Dispersible tablets
Each dispersible tablet contains:
Deferasirox 250 mg

Deferasirox Teva 500mg
Dispersible tablets
Each dispersible tablet contains:
Deferasirox 500 mg
Inactive ingredients and allergens in the preparation: see section 6 "Additional information".
Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine.
If you have additional questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness/medical condition is similar.

1. What is the medicine intended for?

- For treatment of chronic iron overload due to blood transfusions in adults and children (2 years old and older).
- For treatment of chronic iron overload unrelated to blood transfusions in thalassemia patients 10 years old and older.

Therapeutic class: Iron chelating agent
Repeated blood transfusions are sometimes required in patients with certain types of anemia, such as thalassemia, sickle-cell anemia and myelodysplastic syndromes. However, repeated blood transfusions may cause the accumulation of excessive iron. That is because blood contains iron and the body does not have a natural pathway for removal of the excessive iron received with the blood transfusions. In thalassemia patients that are not dependent on blood transfusions, an iron overload may develop over time mainly due to increased absorption of iron from food as a reaction to low blood cells counts. Over time, the excessive iron can damage vital organs such as the liver and the heart.
Medicines of the iron chelators type are used for removal of the excessive iron and decrease the risk for damage to body organs.
Deferasirox Teva captures and removes excessive iron which is then excreted mainly in the stool.

2. Before using the medicine

☒ Do not use this medicine if:

- You are sensitive (allergic) to deferasirox or to any of the other ingredients this medicine contains as listed in section 6 – "Additional information".

If this applies to you, **tell your doctor before taking** Deferasirox Teva. If you think that you are allergic, consult with your doctor.

- You have a moderate or severe kidney disease.
- You are currently taking another iron chelator.

❗ Special warnings regarding the use of the medicine
Before treatment with Deferasirox Teva, inform the doctor if:

- You have an advanced-stage myelodysplastic syndrome (MDS - decreased production of blood cells by the bone marrow) or an advanced-stage cancer. Using Deferasirox Teva in these conditions is not recommended.
- You have liver or kidney problem.
- You are suffering from a cardiac problem due to iron overload.
- You observe a significant decrease in urine output (a sign of a kidney problem).
- You have a severe rash, or breathing difficulties and dizziness or swelling, mostly of the face and throat (signs of a severe allergic reaction, see also section 4 "Side effects").
- You experience a combination of any of the following symptoms: rash, skin reddening, blisters on the lips, eyes or mouth, skin exfoliation, high fever, flu-like symptoms, enlarged lymph nodes (signs of a severe skin reaction, see also section 4 "Side effects").
- You sense a combination of drowsiness, pain in the upper-right part of the abdomen, yellowing or increase in yellowing of the skin or eyes and dark urine (signs of liver problems).
- You vomit blood and/or you have black stool.
- You experience frequent abdominal pain, especially after eating or taking Deferasirox Teva.
- You have frequent heartburns.
- You have low platelet count or white blood cell count in your blood tests.
- You have blurry vision.
- You have diarrhea or are vomiting.

If any of the above conditions apply to you, inform the doctor immediately.
❗ Elderly population (age 65 and older)
Adults aged 65 years and older can use Deferasirox Teva in the same dose as other adults.
Elderly patients may experience more side effects (mainly diarrhea) than younger patients. They should be closely monitored by their doctor to identify side effects, which may require dosage adjustment.
❗ Children and adolescents
Deferasirox Teva can be used in adolescents and children over 2 years of age for treatment of chronic iron overload due to blood transfusions and over 10 years of age for treatment of chronic iron overload unrelated to blood transfusions in thalassemia patients. As the patient grows, the doctor will adjust the dosage.
❗ Tests and follow-up
During the treatment you should have blood and urine tests regularly. These tests will monitor the iron level in your body (blood ferritin levels) in order to see whether Deferasirox Teva is acting properly. The tests will also monitor your kidney function (blood creatinine levels, presence of protein in the urine) and your liver function (blood transaminases levels, bilirubin and alkaline phosphatase). You may also have MRI (Magnetic Resonance Imaging) tests in order to determine the amount of iron in your liver. The doctor will take these tests into consideration when he decides what dosage of Deferasirox Teva is the most appropriate for you, and will use these tests to decide when you should stop taking Deferasirox Teva.
You should have hearing and visual tests before starting the treatment and once a year during the treatment as a precaution.
In children, their growth in height and weight should be followed, as well as their sexual development, once a year.
In every question about how does Deferasirox Teva work or why has it been prescribed for you, contact a doctor, a pharmacist or a member of the medical staff.
❗ Drug-drug interactions:
If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Other iron chelators, which should not be taken together with Deferasirox Teva.
- Antacids (medicines used for treatment of heartburn) which contain aluminum, that should not be taken at the same time during the day with Deferasirox Teva.

Especially inform the doctor or pharmacist if you are taking:
Cyclosporine (used for prevention of transplanted organ rejection or in other conditions, e.g. rheumatoid arthritis or contact dermatitis).
Simvastatin (used for lowering cholesterol).
Certain analgesics or anti-inflammatory medicines (e.g. aspirin, ibuprofen, corticosteroids).
Oral bisphosphonates (used for treatment of osteoporosis).
Anticoagulants (used for prevention or treatment of formation of blood clots).
Hormonal contraceptives (preparations for pregnancy prevention).
Bepridil, ergotamine (used for cardiac problems and migraines).
Repaglinide (used for treatment of diabetes).
Rifampicin (used for treatment of tuberculosis).
Phenytoin, phenobarbital, carbamazepine (used for treatment of epilepsy).
Ritonavir (used for treatment of HIV infection).
Paclitaxel (used for treatment of cancer).
Theophylline (used for treatment of respiratory diseases, such as asthma).
Clozapine (used for treatment of psychiatric disorders, such as schizophrenia).
Tizanidine (used as a muscle relaxant).
Cholestyramine (used for lowering blood cholesterol levels).
Additional tests may be required to monitor the level of some of the medicines in your blood.
❗ Using Deferasirox Teva and food
Deferasirox Teva should be taken on an empty stomach and you should wait at least 30 minutes before eating anything. Same time each day is preferred.
The tablets should be dissolved in a glass of water, apple juice or orange juice. The tablets should not be dissolved in fizzy drinks or milk (see also "How to take Deferasirox Teva").
❗ Pregnancy and breastfeeding
Deferasirox Teva is not recommended during pregnancy unless it is clearly necessary. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask the doctor for advice before taking the medicine.
Breastfeeding is not recommended during treatment with Deferasirox Teva.
If you are using contraceptive pills or a contraceptive patch, you should use an additional or a different type of contraceptive (such as a condom), since Deferasirox Teva may decrease the efficacy of contraceptive pills and patches.
❗ Driving and operating machinery
If you feel dizziness after taking Deferasirox Teva, do not drive a vehicle or operate tools or machines until your feeling returns to normal.
❗ Important information about some ingredients of the medicine
Deferasirox Teva tablets contain lactose (milk sugar). If you have intolerance to certain types of sugars, inform the doctor before taking Deferasirox Teva.
Each dispersible tablet of Deferasirox Teva 125 mg contains about 85 mg of lactose monohydrate.
Each dispersible tablet of Deferasirox Teva 250 mg contains about 170 mg of lactose monohydrate.
Each dispersible tablet of Deferasirox Teva 500 mg contains about 341 mg of lactose monohydrate.
This preparation contains less than 23 mg of sodium in each dispersible tablet, and is therefore considered sodium-free.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
Treatment with Deferasirox Teva will be performed under supervision of a doctor who is experienced in treating a condition of excessive iron caused by blood transfusions.
The accepted dosage:
The dosage and treatment regimen will be determined only by the doctor. The dosage of Deferasirox Teva is related to body weight in all patients. The doctor will calculate the dosage you need and will tell you how many tablets to take each day.
The generally accepted daily dosage in the beginning of treatment is:

- 20 mg for each kg of body weight for patients that are receiving blood transfusions regularly. Your doctor may recommend a higher or lower initial dosage based on your personal treatment needs.
- 10 mg for each kg of body weight for patients that are not receiving blood transfusions regularly.

Based on your reaction to the treatment, the doctor can later adjust the treatment for you with a higher or lower dosage.
The maximum daily dosage is:

- 40 mg for each kg of body weight for patients that are receiving blood transfusions regularly.
- 20 mg for each kg of body weight for patients that are not receiving blood transfusions regularly.
- 10 mg for each kg of body weight for children and adolescents that are not receiving blood transfusions regularly.

Do not exceed the recommended dose.
When should you take Deferasirox Teva:

- Deferasirox Teva should be taken once a day, every day, at approximately the same time.
- The tablets should be taken on an empty stomach and you should wait at least 30 minutes before eating anything.

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


Put the tablet/s in a glass of water, apple juice or orange juice (100-200 ml).


Stir until the tablet/s dissolve/s completely. The liquid in the glass will appear cloudy.


Drink the entire contents of the glass, and then add some water or juice to what was left in the glass, stir and drink that too.

The tablets should not be dissolved in fizzy drinks or milk.
Do not chew, break or crush the tablets; the tablets should not be swallowed whole.
Duration of treatment:
You should continue to take Deferasirox Teva every day, as long as the doctor instructs you to do that. This treatment is prolonged, and may take months or years. The treating doctor will follow your condition regularly in order to make certain that the treatment affects you properly (see also: "tests and follow-up"); if you have questions about the duration of treatment, contact the treating doctor.
If you have taken an overdose or by mistake a child or another person has swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you. Medical attention may be required.
If you forgot to take the medicine:
If you forgot to take this medicine at the scheduled time, do it the moment you remember on the same day. Take the next dose at the scheduled time and consult a doctor.
Do not take a double dose on the next day in order to compensate for the forgotten tablet/s. Follow the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.
If you stop taking the medicine:
Do not stop the treatment with Deferasirox Teva without an explicit order from the doctor. If you stop taking Deferasirox Teva, the excessive iron will no longer be removed from your body (see also "duration of treatment" above).
Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Deferasirox Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them. Most side effects are mild to moderate and will usually subside after several days to several weeks.
Certain side effects may be serious and may require immediate medical attention. These side effects are uncommon (can affect up to 1 out of 100 patients) or rare (can affect up to 1 out of 1000 patients).
Stop taking the medicine and contact a doctor immediately if you or your child experience any of the following conditions:
A severe rash, breathing difficulties and dizziness or swelling, mostly of the face and throat (signs of a severe allergic reaction).
A combination of several of the following symptoms: rash, skin reddening, blisters on the lips, eyes or mouth, skin exfoliation, high fever, flu-like symptoms, enlarged lymph nodes (signs of a severe skin reaction). A significant decrease in urine output (a sign of a kidney problem). A combination of drowsiness, pain in the upper-right part of the abdomen, yellowing or increase in yellowing of the skin or eyes and dark urine (signs of liver problems). Bloody vomit and/or black stool. Frequent abdominal pains, especially after eating or taking Deferasirox Teva. Frequent heartburns. Partial vision loss. Severe pain in the upper part of the abdomen (pancreatitis).
Certain side effects may become serious. These side effects are uncommon, **tell the doctor as soon as possible if:**
You are suffering from a blurry or cloudy vision.
You are suffering from impaired hearing.
Additional side effects:
If one or more of the following side effects is severely affecting you, contact the doctor.
Very common side effects (may affect more than 1 out of 10 patients):
Influence on kidney function tests.
Common side effects (may affect up to 1 out of 10 patients):
Gastrointestinal disturbances such as nausea, vomiting, diarrhea, abdominal pain, swelling, constipation, digestive difficulties. Rash. Headache. Influence on liver function tests. Itching. Influence on urine tests (protein in urine).
Uncommon side effects (may affect up to 1 out of 100 patients):
Dizziness. Fever. Sore throat. Swelling in the arms and legs. Skin discoloration. Anxiety. Sleep disturbances. Tiredness.
Side effects with unknown incidence (incidence cannot be estimated from existing data):
A decrease in: the number of blood cells related to blood coagulation (thrombocytopenia), the number of red blood cells (severe anemia), the number of white blood cells (neutropenia) or in the number of all blood cell types (pancytopenia). Hair loss. Kidney stones.
Low urine output. Perforation of the stomach or intestinal wall, which may cause pain and nausea. Severe pain in the upper part of the abdomen (pancreatitis).
Abnormal level of acid in the blood.
If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
Reporting side effects
Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
store below 25°C.

6. Additional 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 does the medicine look like and what are the contents of the package:
Deferasirox Teva is marketed as dispersible tablets in a package size of 30 tablets.
Deferasirox Teva 125 mg: a round, flat, white-beige tablet. On one side it is embossed with the number "77", and on the other side it is embossed with the number "438".
Deferasirox Teva 250 mg: a round, flat, white-beige tablet. On one side it is embossed with the number "77", and on the other side it is embossed with the number "439".
Deferasirox Teva 500 mg: a round, flat, white-beige tablet. On one side it is embossed with the number "77", and on the other side it is embossed with the number "440".
License holder and the address: Abic Marketing Ltd. P.O.B 8077 Netanya, Israel.
Name and address of the manufacturer: Teva Pharmaceutical Industries Ltd., P.O. box 3190, Petah Tikva.
This leaflet was checked and approved by the Ministry of Health in: December 2018
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 161 12 34651, 161 13 34650, 161 14 34653.