Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed with a doctor's prescription only

DEFERASIROX TARO ® 125 mg Dispersible tablets for oral suspension	**DEFERASIROX TARO ® 250 mg Dispersible tablets for oral suspension**	**DEFERASIROX TARO ® 500 mg Dispersible tablets for oral suspension**
Each dispersible tablet contains: deferasirox 125 mg	Each dispersible tablet contains: deferasirox 250 mg	Each dispersible tablet contains: deferasirox 500 mg

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'**.**

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your or 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 to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- To treat chronic iron overload caused by blood transfusions (transfusional hemosiderosis) in adults and children (aged 2 years and older).
- To treat chronic iron overload in patients with non-transfusion- dependent thalassemia aged 10 years and older.

Therapeutic group: iron chelating agent.

Repeated blood transfusions are sometimes necessary in patients suffering from certain types of anemia such as thalassemia, sickle-cell disease and myelodysplastic syndromes (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 Taro traps and removes excess iron, which is then excreted mainly in the stool.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to deferasirox or to any of the other ingredients in this medicine (see section 6 'Additional information'). If this applies to you, **tell the doctor before taking Deferasirox Taro**. If you think you are allergic, consult the doctor.
- You have moderate or severe kidney disease.
- You are currently taking another iron chelator medicine.

Deferasirox Taro 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 about using this medicine

Before using Deferasirox Taro, tell your doctor if:
- You have a liver or kidney problem.
- You have a cardiac problem caused by iron overload.
- You notice a marked decrease in your 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, see also 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, see also 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 your blood, which may be associated with liver or kidney problems, see also section 4 'Side effects').
- You vomit blood and/or have black stools.
- You frequently have abdominal pain, particularly after eating or taking Deferasirox Taro.
- You have frequent heartburn.
- 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.

Children and adolescents
Deferasirox Taro can be used in children and adolescents aged 2 years and older to treat chronic iron overload caused by blood transfusions and aged 10 years and older to treat non-transfusion-dependent chronic iron overload in thalassemia patients.
The doctor will adjust the dosage according to the child’s growth.
Deferasirox Taro 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 Taro is working properly. The tests will also monitor kidney function (blood creatinine levels, presence of protein in the urine) and liver function (levels of transaminases, bilirubin and alkaline phosphatase in your blood). Your doctor may ask you to undergo a kidney biopsy, if he/she suspects significant kidney damage. You may also have 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 dose of Deferasirox Taro is best for you and will also use these tests to decide when you should stop taking Deferasirox Taro.

You must undergo hearing and vision tests before beginning treatment and once a year during the course of treatment, as a precautionary measure.

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.
- Deferasirox Taro must not be combined with other iron chelating preparations.
- Do not take antacids (medicines used to treat heartburn) containing aluminum at the same time of day as Deferasirox Taro.

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 formation of blood clots or treat 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 transplant)
- 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.

Using this medicine and food
Take Deferasirox Taro 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 Taro').

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

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 Taro 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 Taro may reduce the effectiveness of hormonal contraceptives.
Breastfeeding is not recommended during treatment with Deferasirox Taro.

Driving and using machines
If you feel dizzy after taking Deferasirox Taro, 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 this medicine's ingredients
Deferasirox Taro tablets contain lactose (milk sugar) and sodium.
If you have been told by your doctor that you have an intolerance to certain sugars, inform the doctor before taking Deferasirox Taro.
The medicine contains less than 1 mmol (23 mg) sodium per tablet, and is therefore considered essentially 'sodium-free'.

3. HOW TO USE THIS 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 or about how to take this medicine.
Treatment with Deferasirox Taro will be overseen by a doctor who is experienced in the treatment of iron overload.
Only your doctor will determine your dose and how you should take this medicine. In all patients, the dosage of Deferasirox Taro 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 aged under 18 years not regularly receiving blood transfusions.

Do not exceed the recommended dose.

Treatment duration:
Continue taking Deferasirox Taro 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 duration of treatment, contact the doctor.

When to take Deferasirox Taro:

- Take Deferasirox Taro once a day, every day, at about the same time.
- Take the tablets on an empty stomach.
- Then wait at least 30 minutes before eating any food.

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

How to take Deferasirox Taro?

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

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

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 Taro 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 see a doctor or go 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 forget 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 forgotten tablet(s).

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine

Do not stop treatment with Deferasirox Taro without explicit instruction from the doctor. If you stop taking Deferasirox Taro, the excess iron will no longer be removed from your body (also see above 'Treatment duration').

Do not take medicines in the dark! Check the label and dose every time you take 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

As with any medicine, use of Deferasirox Taro may cause side effects in some users. Do not be alarmed by this 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)
- 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 stools
- frequent abdominal pain, particularly after eating or taking Deferasirox Taro
- frequent heartburn
- 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 - affect more than 1 in 10 users
- abnormal tests related to kidney function

Common side effects - affect up to 1 in 10 users
- 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 - affect up to 1 in 100 users

- 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 (the frequency of these effects has not been established yet)

- a decrease in the number of blood cells involved in blood clotting (thrombocytopenia), in the number of red blood cells (anemia aggravated), in the number of white blood cells (neutropenia) or in the number of all kinds of blood cells (pancytopenia)
- hair loss
- kidney stones
- low urine output
- a tear in the stomach or intestine wall that may cause pain and nausea
- severe upper abdominal pain (pancreatitis)
- abnormal level of acid in the blood

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link:
https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
Storage conditions: Store below 25°C.
Shelf-life after opening for the bottle package: 30 days.
Do not use a package that is damaged or shows signs of tampering.

Do not throw away 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. ADDITIONAL INFORMATION

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

lactose monohydrate, crospovidone, microcrystalline cellulose, povidone, magnesium stearate, colloidal silicon dioxide, sodium lauryl sulphate.

What the medicine looks like and the contents of the pack:
Deferasirox Taro dispersible tablets are packed in bottles containing 30 or 60 tablets, or in a blister pack containing 30 tablets.
The bottle is child resistant.
Not all pack sizes may be marketed.
Deferasirox Taro 125 mg, 250 mg and 500 mg tablets are white to off-white, round and flat, with beveled edges and embossed with '568', '569' and '570', respectively, on one side.

Registration holder's name and address:
Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761.

Manufacturer’s name and address:
Sun Pharmaceutical Industries Ltd, Dadra and Nagar Haveli, India

Revised in December 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health National Drug Registry:
Deferasirox Taro 125 mg: 171 09 36122
Deferasirox Taro 250 mg: 171 10 36123
Deferasirox Taro 500 mg: 171 11 36124