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

Deferiprone Taro 1000 mg

Film-coated tablets

Active ingredient
Each tablet contains 1000 mg deferiprone.

Inactive ingredients and allergens in this medicine: see 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 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?

For the treatment of iron overload in patients over 6 years old who suffer from thalassemia major when deferoxamine therapy is contraindicated or inadequate.

Therapeutic group: iron-binding agents (chelators).

2. Before using this medicine

Do not use this medicine:

if you are sensitive (allergic) to deferiprone or to any of this medicine's ingredients (see section 6)
if you are pregnant and/or breastfeeding
in children under the age of 6
if you have or have ever had neutropenia (low white blood cell (neutrophil) count)
if you have or have ever had agranulocytosis (very low white blood cell (neutrophil) count)
if you are currently being treated with medicines known to cause neutropenia or agranulocytosis.

Special warnings about using this medicine

The most serious side effect that may occur as a result of taking Deferiprone Taro is very low white blood cell (neutrophil) count. This condition, known as severe neutropenia or agranulocytosis, has occurred in 1 to 2 out of 100 people who have taken deferiprone in clinical studies. Because white blood cells help your body to fight infection, a low neutrophil count may place the patient at risk of developing a serious and potentially life-threatening infection. To monitor for neutropenia, your doctor will ask you to have a blood test performed regularly (to check your white blood cell count), as frequently as every week, for as long as you are being treated with Deferiprone Taro. It is very important for you to undergo all of these tests. If you get any symptoms of infection such as fever, sore throat or flu-like symptoms, immediately seek medical attention. Your white blood cell count must be checked within 24 hours in order to detect potential agranulocytosis.

If you are HIV positive or if your liver or kidney function is impaired, your doctor may recommend additional tests.

Before starting treatment with Deferiprone Taro, tell your doctor if you suffer, or have suffered in the past, from impaired function of the liver, kidneys, blood system (low white blood cell count).

Children and adolescents
This medicine is not to be used in children under 6 years old.

Tests and follow-up
Your doctor will ask you to come in for tests to monitor iron overload in your body and may also ask you to undergo liver biopsies.

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. Particularly if you are taking or intend to take:

- preparations containing vitamin C.

Do not take heartburn medicines (antacids containing aluminium) while using Deferiprone Taro.
Do not take medicines known to cause neutropenia or agranulocytosis (see “Do not use this medicine”).

Using this medicine and food
Deferiprone Taro can be taken with or without food.

Pregnancy and breastfeeding
Pregnancy
Do not use this medicine if you are pregnant or are planning to become pregnant. This medicine could seriously harm your baby.
Use effective contraception for as long as you are being treated with Deferiprone Taro. Ask your doctor which method is best for you. If you become pregnant while taking Deferiprone Taro, stop taking the medicine immediately and tell your doctor.
Breastfeeding
Do not use Deferiprone Taro if you are breastfeeding.

Driving and using machines
No studies have been performed regarding the effect of the medicine on driving and using machines.

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. Only your doctor will determine your dose and how you should take this medicine.
The amount of Deferiprone Taro that you take will depend on your weight. The usual dosage is 25 mg/kg 3 times a day, for a daily total of 75 mg/kg. The total daily dose should not exceed 100 mg/kg.
Take your first dose in the morning, the second dose midday, and the third dose in the evening. Deferiprone Taro can be taken with or without food; however, you may find it easier to remember to take Deferiprone Taro if you take it with your meals.

Do not exceed the recommended dose.

Directions for use
Do not chew the medicine! Swallow the medicine with a small amount of water. If necessary, the tablet may be halved. If you suffer from nausea or vomiting due to use of the medicine, taking it with food may improve how you feel.

If you have accidentally taken a higher dose
There are no reports of severe overdose with deferiprone. If you have accidentally taken an overdose, or if a child has accidentally swallowed some medicine, go to a hospital emergency room immediately and bring the medicine package with you.

If you forget to take Deferiprone Taro
Deferiprone Taro is highly effective if no doses of the medicine are missed. If you do miss a dose, take the medicine as soon as possible and take the next dose at its regularly scheduled time. If you miss more than one dose, do not take a double dose to make up for missed doses; go back to your normal schedule. Do not change the daily dose without first consulting your doctor.
Adhere to the treatment as recommended by your doctor.

How can you contribute to the success of the treatment?
Complete the full course of treatment as instructed by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> 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, using Deferiprone 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.

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Very common side effects (affect more than one in ten users):
- abdominal pain
- nausea
- vomiting
- reddish/brown discolouration of urine.

If you suffer from nausea or vomiting, it may help to take Deferiprone Taro with food.
Discoloured urine is a very common side effect and is not harmful.

Common side effects (affect up to one in ten users):
- low white blood cell count (agranulocytosis and neutropenia)
- headache
- diarrhoea
- increase in liver enzymes
- fatigue
- increase in appetite.

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- allergic reactions including skin rash or hives.

Events of joint pain and swelling have been reported, ranging from mild pain in one or more joints to severe disability. In most cases, the pain disappeared while the patient continued taking deferiprone.

Data from monitoring deferiprone use after its approval for marketing indicate neurological disorders (such as tremors, walking disorders, double vision, involuntary muscle contractions, problems with movement coordination), which were reported in children who as part of a clinical trial received a dosage that was more than double the maximum recommended dose of 100 mg/kg/day for a period of several years, and were also observed in children who received a standard dose of deferiprone. The children recovered from these symptoms after treatment with deferiprone was stopped.

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 links to an online form for reporting side effects. 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.

Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Tablet core:
Crospovidone type B, methylcellulose, magnesium stearate.
Tablet coating:
Hydroxypropyl methylcellulose 2910E, titanium dioxide, copovidone, polydextrose, polyethylene glycol, medium chain triglycerides.

What the medicine looks like and contents of the pack:
Oval, white film-coated tablet debossed on one side with a score line that has "T" on its left and "1K" on its right. The other side is plain.
Deferiprone Taro 1000 mg is packaged in a child-resistant plastic bottle containing 50 tablets and a desiccant.

Name and address of registration holder and manufacturer: Taro Pharmaceutical Industries Ltd., 14 HaKitor St., Haifa Bay 2624761.

Revised in January 2024.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 175-24-37393-99

For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code:

https://israeldrugs.health.gov.il/#!/medDetails/175%2024%2037393%2099

For a printed copy of the patient information leaflet in English, please contact the registration holder by email info@taro.com or by phone 1-800-464-664.