

## **Cipla Deferasirox: Important information for patients about your treatment and possible side effects**

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Please keep this document safe for future reference. This booklet is only intended for patients that have been prescribed Cipla deferasirox. It contains important information, including how to take Cipla Deferasirox the right way, why monitoring your treatment is important, and which medicines you can take while on Cipla Deferasirox.

For full safety guidance, please refer to the Consumer Medicine Information, you can ask your pharmacist for a copy or download it from the TGA website.

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=deferasirox>

You can help by reporting any side effects you may get. See <https://aems.tga.gov.au> for how to report side effects.

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## **Glossary**

### **Beta thalassaemia major**

An inherited blood disorder in which patients do not have enough normal haemoglobin in the blood.

### **Creatinine**

A chemical waste product produced by the muscles. Healthy kidneys filter creatinine and other waste products from the blood and these are excreted, in the form of urine.

It is used to assess how well your kidneys are functioning.

### **Ferritin**

Your blood level of ferritin indicates the amount of iron in your blood.

### **Myelodysplastic syndrome (MDS)**

A blood disorder that causes a drop in the number of healthy blood cells.

### **Other anaemias**

Low levels of haemoglobin in the blood.

### **Sickle cell disease – a group of inherited conditions that affect red blood cells**

People with sickle cell disease produce unusually shaped red blood cells that can cause problems because they don't live as long as healthy blood cells and they can become stuck in blood vessels.

## **My background information**

Your background information is helpful for both you and your doctor when planning your treatment with Cipla Deferasirox. Ask your doctor if you need help answering these questions.

### **General information**

First name \_\_\_\_\_

Last name \_\_\_\_\_

Date of birth \_\_\_\_\_

Diagnosis \_\_\_\_\_

Have I been given blood transfusions? If so, how many and how often?

\_\_\_\_\_

Do I have any other health issues?

\_\_\_\_\_

\_\_\_\_\_

Am I taking any medicine right now for other health issues?

\_\_\_\_\_

\_\_\_\_\_

Do I have any allergies?

\_\_\_\_\_

\_\_\_\_\_

## Starting Cipla Deferasirox

You can start tracking your progress once your doctor decides on your target blood level of ferritin and dose of Cipla Deferasirox. Work with your doctor to fill in your treatment goals and other information, below.

**Date:** \_\_\_\_\_

**My current ferritin level:** \_\_\_\_\_

My treatment goal is to:

Reduce my ferritin level to \_\_\_\_\_

My weight: \_\_\_\_\_

My Cipla Deferasirox dosing regimen

- What is my dose? \_\_\_\_\_
- How many tablets will I take each day? \_\_\_\_\_
- When will I take my medication each day? \_\_\_\_\_

**Please note:** If you have non-transfusion-dependent thalassaemia (NTDT), liver iron concentration (LIC) is the preferred method to measure the amount of iron you have.

**Notes:** Write down any notes or questions from your visit.

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## What is deferasirox?

Deferasirox is an iron chelator (or a “chelating” agent), which is a medicine used to help remove excess iron in the body.

## How does this medicine work?

Deferasirox is an orally active chelator that is highly selective for iron. It binds iron with high affinity and increases excretion of iron, mainly in the faeces. Deferasirox has very low affinity for zinc and copper and does not cause constant low serum levels of these metals.

## Why was I prescribed this medicine?

Many kinds of condition need blood transfusions. Some of these are:

- Beta thalassaemia major – an inherited blood disorder in which patients do not have enough normal haemoglobin in the blood
- Sickle cell disease – a group of inherited conditions that affect red blood cells. People with sickle cell disease produce unusually shaped red blood cells that can cause problems because they don't live as long as healthy blood cells and they can become stuck in blood vessels
- Myelodysplastic syndrome (MDS) – a blood disorder that causes a drop in the number of healthy blood cells
- Other anaemias (low levels of haemoglobin in the blood)

If you have one of these conditions, you've probably been given a few transfusions. Transfusions have the healthy red blood cells your body needs and can help you feel better.

Every transfusion you are given contains iron. Iron is important because red blood cells use it to carry oxygen around your body. However, the body does not have its own way of removing extra iron.

The amount of iron builds up with each transfusion. This causes extra iron in your body, called **chronic iron overload**. Too much iron can be harmful and damage organs like your heart and liver.

Cipla Deferasirox is also used to treat patients who have iron overload associated with their thalassaemia syndromes, but who are not transfusion dependent. In patients with non-transfusion-dependent thalassaemia syndromes, iron overload may develop over time due to increased absorption of dietary iron in response to low blood cell counts.

Over time, this excess iron can damage important organs such as the liver and heart.

It is important to remove this extra iron to keep your iron at a safe, healthy level.

## **How do I take Cipla Deferasirox?**

It is important to follow all directions given to you by your doctor or pharmacist carefully.

### **What dose will I take?**

Your prescribed dose of Cipla Deferasirox is based on your weight, current iron level, liver and kidney function, and how often you get transfusions. Your doctor will calculate the dose you need and tell you how many tablets to take each day.

The usual starting dose is 14 mg per kilogram body weight each day for patients receiving regular blood transfusions.

For patients NOT receiving regular blood transfusions, the usual starting dose is 7 mg per kilogram body weight.

A higher or lower starting dose may be recommended by your doctor based on your individual treatment needs.

Depending on your response, your doctor may increase the dose to a maximum 28 mg per kilogram body weight each day if you receive regular blood transfusions or 14 mg per kilogram body weight if you are NOT receiving regular blood transfusions.

### **Which tablet(s) will I take?**

Cipla Deferasirox comes in different tablet sizes (as mentioned below), and you may need to take more than one. Your doctor will tell you how many tablets and which size(s) you should take each day.

90 mg film-coated tablets: Light pink oval biconvex film-coated tablet, debossed with 'C391' on one side and plain on the other.

180 mg film-coated tablets: Light pink oval biconvex film-coated tablet, debossed with 'C392' on one side and plain on the other.

360 mg film-coated tablets: Light pink oval biconvex film-coated tablet, debossed with 'C393' on one side and plain on the other.

Cipla Deferasirox comes in packs of 30 film-coated tablets in blister packs.

### **When and How to take Cipla Deferasirox**

- Cipla Deferasirox film-coated tablets should be taken once a day, preferably at the same time each day with some water.
- Take the tablets either on an empty stomach or with a light meal.
- Do not take the tablets with a high fat meal.

- If you cannot swallow the tablets whole, you can crush them. Then sprinkle all of it onto soft food like yogurt or apple sauce (apple puree). You should then eat it all immediately. Do not keep any to have later.

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

Other oral formulation (e.g. dispersible tablets) has different doses and is taken in a different way.

### **What if I forget to take my dose?**

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

### **What if I take more Cipla Deferasirox tablets than I should?**

If you think that you have used too much Cipla Deferasirox, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you have taken too much Cipla Deferasirox, you may experience effects such as abdominal pain, nausea, vomiting, headache, diarrhoea and kidney or liver problems that can be serious.

### **How will my treatment be monitored?**

While taking Cipla Deferasirox, you will have regular laboratory tests. These tests will monitor how you are responding to treatment. Your dose may have to be adjusted up or down based on these test results.

<b>Test</b>	<b>Before starting Cipla Deferasirox</b>	<b>Every month</b>	<b>Once per year</b>
<u>Iron</u>	✓	✓	



Test	Before starting Cipla Deferasirox	Every month	Once per year
Amount of iron in your body (blood level of ferritin)			
<u>Kidney function</u> Blood level of creatinine	✓ You will take this test twice before starting Cipla Deferasirox	✓ For the first month and in the first month after any changes in dose you will be tested once per week; then once per month	
<u>Creatinine clearance</u> (to see how well your kidneys are working)	✓	✓ For the first month and in the first month after any changes in dose you will be tested once per week; then once per month	
Protein in urine*	✓	✓	
<u>Liver function</u> Blood levels of transaminases, bilirubin, alkaline phosphatase	✓	✓ For the first month, you will be tested every 2 weeks; then once per month	
Hearing and vision	✓		✓
Body weight, height and sexual development	✓		✓ Annually in children

\* Patients should be referred to a renal specialist, and further specialised investigations (such as renal biopsy) may be considered if significant renal abnormalities occur.

## Does this medicine have side effects?

All medicines can have side effects, though not all patients experience them. If you do experience any side effects, most of them are minor and temporary and will generally disappear once you get used to treatment. However, some side effects may need medical attention.

Elderly patients may experience more side effects than younger patients.

Common side effects include: nausea, vomiting, diarrhoea, pain in the abdomen and skin rash. These reactions are dose-dependent, mostly mild to moderate, generally temporary and mostly go away even if treatment is continued.

Your kidney and liver function will be tested before you start Cipla Deferasirox and you will be monitored regularly during treatment. (See table on the previous page.)

STOP taking Cipla Deferasirox and seek medical help immediately if you or your child experience any of the following symptoms which may be signs of an allergic reaction:

- difficulty in breathing and swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

For more details on side effects and serious side effects, please see the Consumer Medicine Information. This can be accessed from the following website: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=cmi&q=deferasirox>

## **What about other medicines?**

Cipla Deferasirox must not be taken with other iron chelators.

Antacids (medicines used to treat heartburn) containing aluminium should not be taken at the same time of day as Cipla Deferasirox.

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor may need to test the level of some of these medicines in your blood. Your doctor will take these tests into consideration when deciding on the most suitable dose of these medicines for you.

You may need to take different medicines. Your doctor and pharmacist have more information.

## **My progress with Cipla Deferasirox**

### **My treatment goal**

The goal of deferasirox treatment is to have a healthy amount of iron in your body. Each month you will visit your doctor to track your progress toward your treatment goal.

Your doctor will set your treatment goal based on the results of a blood ferritin test. This test gives your current ferritin level and tells your doctor how much iron is in your body. Your doctor will want to either lower your ferritin level or keep it where it is.

### **My Cipla Deferasirox dose**

The dose of Cipla Deferasirox is related to body weight for all patients. Your doctor will calculate the dose you need and tell you how many tablets to take each day.

Your doctor may decide to change your dose based on your ferritin level, other laboratory tests, or how often you get transfusions.

After taking Cipla Deferasirox for 3 to 6 months, check with your doctor that you are making progress as planned. If you are not, ask your doctor about his/her plan for helping you reach your treatment goal.

### **Between each visit**

Other important events may occur between doctor visits. You should keep a record of them and share them with your doctor. They include:

- Side effects
- Other medicines
- Any deviation from the prescribed dose

### **How to report a side effect**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <https://aems.tga.gov.au/>. Adverse events should also be reported to Cipla via email at [drugsafety@Cipla.com](mailto:drugsafety@Cipla.com) or call at 1800 569 074. By reporting side effects, you can help provide more information on the safety of this medicine.