

# MY DEFERASIROX-TEVA<sup>®</sup> HANDBOOK (deferasirox)

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

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

This booklet is for people who have been prescribed DEFERASIROX-TEVA<sup>®</sup> (deferasirox). It provides answers to some common questions about DEFERASIROX-TEVA but should not replace the advice of your doctor. If you have any concerns about your treatment or condition, please talk to your doctor.

## INTRODUCTION

DEFERASIROX-TEVA is a formulation of a medicine called deferasirox. Deferasirox is used to remove excess iron from the body.

This handbook contains important information about DEFERASIROX-TEVA.

This book will provide information on how to take DEFERASIROX-TEVA the right way and also provides information on monitoring your treatment, possible side effects, and taking other medicines while on DEFERASIROX-TEVA.

A copy of the Consumer Medicine Information can be downloaded from the TGA website: <https://www.tga.gov.au/consumer-medicines-information-cmi> and search for DEFERASIROX-TEVA

## DEFERASIROX-TEVA TABLETS



Tablets displayed are not actual size.

Take the tablets either on an empty stomach or with a light meal. Tablets should not be taken with a high fat meal.

If you cannot swallow the tablets whole, you can crush them. Then sprinkle all of it onto soft food.

## WHAT IS DEFERASIROX-TEVA?

DEFERASIROX-TEVA helps to remove excess iron from the body. Because of this, it is known as an “iron chelator” or a “chelation agent”.

## WHY WAS I PRESCRIBED DEFERASIROX-TEVA?

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

- $\beta$ -thalassaemia major
- Sickle cell disease, or SCD
- Lower-risk myelodysplastic syndromes, or MDS
- Other anaemias

If you have one of these conditions, you’ve probably received several blood 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, and this extra iron in your body may lead to a condition called **chronic iron overload**. Too much iron can be harmful and damage organs like your heart and liver.

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

## HOW DOES DEFERASIROX-TEVA WORK?

DEFERASIROX-TEVA works by a process called “chelation”.

After swallowing, DEFERASIROX-TEVA enters your blood and “captures” extra iron available.

## WHAT IS DEFERASIROX-TEVA USED FOR?

DEFERASIROX-TEVA is used to treat a condition called iron overload, which happens when the body has too much iron caused by repeated blood transfusions.

The body has no natural way to remove excess iron which comes with blood transfusions.

DEFERASIROX-TEVA is also used to treat people who have iron overload associated with their thalassaemia syndromes, but who do not need blood transfusions. In these people, iron overload may develop over time due to increased absorption of iron from food.

## HOW DO I TAKE DEFERASIROX-TEVA?

### WHAT DOSE WILL I TAKE?

Your prescribed dose of DEFERASIROX-TEVA is based on your weight, current iron level, liver and kidney function, and how often you receive transfusions.

If you are changing from a different medication to DEFERASIROX-TEVA, your doctor may choose your DEFERASIROX-TEVA dose based on how much of the previous medication you were taking.

### WHICH TABLET(S) WILL I TAKE?

DEFERASIROX-TEVA comes in different tablet sizes, 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.

There are multiple forms of deferasirox tablets available on the market. Each has a specific shape and colour and is taken differently, so it is important to follow your doctor’s instructions carefully.

## HOW AND WHEN TO TAKE DEFERASIROX-TEVA

You have been prescribed DEFERASIROX-TEVA film coated tablets. These tablets are blue and oval-shaped and should be taken once a day, by swallowing whole on an empty stomach or with a light meal. If you are unable to swallow whole tablets, DEFERASIROX-TEVA film coated tablets may be crushed and sprinkled onto soft food. You should immediately and completely consume the entire amount and should not store any for future.

### WHAT IF I FORGET TO TAKE MY DOSE?

If you miss taking a dose of DEFERASIROX-TEVA, you should still take it when you remember, even if it is later in the day. Take your next dose as scheduled. Do not take a double dose on the next day to make up for the forgotten dose.

### WHAT IF I TAKE MORE DEFERASIROX-TEVA THAN I SHOULD?

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you have taken too much DEFERASIROX-TEVA, or if anyone else accidentally takes your tablets. Show them the pack of DEFERASIROX-TEVA as medical treatment may be necessary. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy. If you have taken too much DEFERASIROX-TEVA, 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 DEFERASIROX-TEVA, you will have regular laboratory tests that will monitor how you are responding to treatment. Your doctor may adjust your dose up or down based on the results of these tests.

Monitoring recommendations for patients prior to and during Deferasirox treatment <sup>1</sup>				
	Before starting Treatment	In first month after initiation of Deferasirox	Monthly	Yearly
Iron Serum Ferritin	✓		✓	
Kidneys Serum creatinine and/or creatinine clearance	✓ <b>Blood test twice before starting treatment</b>	Weekly (Also weekly for month after dose change)	✓	
Urine Protein in urine	✓		✓	
Hearing and Vision	✓			✓
Liver Serum transaminases, bilirubin, alkaline phosphatase	✓	Every 2 weeks	✓	
Paediatric Patients: Assess body development such as weight, height and sexual development	✓			✓

## DOES DEFERASIROX-TEVA HAVE SIDE EFFECTS?

Like all medicines, DEFERASIROX-TEVA can have side effects. However, not all patients experience them. The most frequent side effects are mild to moderate and usually go away once you get used to treatment. This can take a few days or weeks.

Common side effects include nausea, vomiting, diarrhoea, pain in the abdomen, bloating, constipation, indigestion, skin rash, headache, itching, fever or symptoms of a cold or flu, cough or sore throat, dizziness, swelling of arms or legs.

Your kidney and liver function will be tested before you start DEFERASIROX-TEVA and will be checked regularly during treatment. (See table on previous page.)

### Some side effects could be serious and need immediate medical attention.

The side effects below do not occur frequently. Stop taking this medicine and tell your doctor right away if you experience any of the following:

- Severe rash or difficulty breathing and dizziness, or swelling mainly of the face and throat (signs of severe allergic reaction);
- Rash, red skin, blistering of lips, eyes or mouth, skin peeling, high fever, flu-like symptoms, enlarged lymph nodes, (signs of severe skin reactions);
- Marked decrease in the amount of urine your body produces (sign of kidney problem);
- Vomiting blood and/or have black stools;
- Tear in the stomach or intestine wall that can be painful and cause nausea;
- A combination of drowsiness, upper-right abdominal pain, yellowing or increased yellowing of your skin or eyes and dark urine (signs of liver problems);
- Frequent heartburn or abdominal pain (ulcers), particularly after eating or taking DEFERASIROX-TEVA;
- Severe upper stomach pain (pancreatitis);
- Blurred, cloudy or partial vision loss;
- Hearing disturbances;
- Sudden back pain or pain on the right side of the abdomen (signs of gallstones).

## WHAT ABOUT OTHER MEDICINES THAT I ALSO NEED TO TAKE FOR MY HEALTH?

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicine you take without a prescription. Your doctor may need to do laboratory tests to monitor these medicines.

### Important medicines to tell your doctor about include, in particular:

- Other iron chelation therapies
- Antacids (medicines used to treat heartburn) containing aluminium, which should not be taken at the same time as DEFERASIROX-TEVA
- Cyclosporine (used to prevent the body from rejecting a transplanted organ or for other conditions, such as rheumatoid arthritis or atopic dermatitis)
- Busulfan (used as treatment prior to bone marrow transplant)
- 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 blood clotting)
- Hormonal contraceptive agents (birth control medicines)
- Repaglinide (used to treat diabetes)
- Rifampicin (used to treat tuberculosis)
- Phenytoin, phenobarbitone, carbamazepine (used to treat epilepsy)
- Ritonavir (used in the treatment of HIV infection)
- Paclitaxel (used in cancer treatment)
- 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 (a medicine used to remove bile acids)
- Midazolam (used as a sedative)
- Other medicines that are processed like theophylline in the body and your doctor should know about include: clozapine, cyclobenzaprine, imipramine, haloperidol, fluvoxamine, mexiletine, naproxen, olanzapine, riluzole, tacrine, tizanidine, zileuton and zolmitriptan.

## CONTRACEPTION

If you are currently using an oral contraceptive or using a patch contraceptive to prevent pregnancy, you should use an additional or different type of contraception (e.g. condom), as DEFERASIROX-TEVA may reduce the effectiveness of oral and patch contraceptives.

## MY PROGRESS WITH DEFERASIROX-TEVA

### 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 goals based on a blood test called a serum ferritin (SEER-um FAIR-it-in), or SF, test. This test tells your doctor how much iron is in your body. Your doctor will want to either lower your SF level or keep it where it is.

### MY DOSE

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

After taking DEFERASIROX-TEVA 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 dosage

## MY TREATMENT NOTES

FIRST NAME \_\_\_\_\_

LAST NAME \_\_\_\_\_

DATE OF BIRTH \_\_\_\_\_

MY DIAGNOSIS \_\_\_\_\_

How many transfusions have I had (if any) and how often?

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List other health issues

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List any medicine I am taking right now for other health issues

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Any allergies?

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DATE \_\_\_\_/\_\_\_\_/\_\_\_\_

MY CURRENT SF LEVEL \_\_\_\_\_

MY GOAL SF LEVEL \_\_\_\_\_

My current weight \_\_\_\_\_

## MY DEFERASIROX-TEVA DOSING REGIMEN

How many tablets will I take each day? \_\_\_\_\_

When will I take my medication each day? \_\_\_\_\_

- I can swallow my tablets whole
- I will crush my tablets and sprinkle them on a soft food such as yoghurt or apple sauce (puréed apple) and eat it immediately

## NOTES

Write down any notes or questions you may have for your doctor visit.

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**References:**

1. DEFERASIROX-TEVA® Approved Product Information, August 2021.
2. DEFERASIROX-TEVA® Consumer Medicine Information, August 2021.

DEFERASIROX-TEVA® is a registered trademark of TEVA Pharmaceutical Industries Ltd.  
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