

DEFERASIROX-TEVA®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using DEFERASIROX-TEVA?

DEFERASIROX-TEVA contains the active ingredient deferasirox. DEFERASIROX-TEVA is used to treat a condition called iron overload, which happens when the body has too much iron. This can occur after repeated blood transfusions.

For more information, see Section [1. Why am I using DEFERASIROX-TEVA?](#) in the full CMI.

2. What should I know before I use DEFERASIROX-TEVA?

Do not use if you have ever had an allergic reaction to DEFERASIROX-TEVA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use DEFERASIROX-TEVA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DEFERASIROX-TEVA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use DEFERASIROX-TEVA?

- Follow all directions given to you by your doctor or pharmacist carefully.
- The dose of DEFERASIROX-TEVA 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.

More instructions can be found in Section [4. How do I use DEFERASIROX-TEVA?](#) in the full CMI.

5. What should I know while using DEFERASIROX-TEVA?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are using DEFERASIROX-TEVA.● Tell your doctor immediately if you notice substantially reduced urine output.● Tell your doctor if you are pregnant or intend to become pregnant while taking this medicine.● Keep all of your doctor's appointments so that your progress can be checked.● Elderly patients should be monitored closely by their doctor.
Things you should not do	<ul style="list-style-type: none">● Do not give this medicine to anyone else, even if their condition seems similar to yours.

<p>Driving or using machines</p>	<ul style="list-style-type: none"> • Be careful driving, operating machinery or doing jobs that require you to be alert until you know how DEFERASIROX-TEVA affects you.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> • Store DEFERASIROX-TEVA in a cool dry place where the temperature is below 25°C, out of direct light. • Keep DEFERASIROX-TEVA in the original container, in a safe place away from children.

For more information, see Section [5. What should I know while using DEFERASIROX-TEVA?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are headaches, stomach or bowel problems and rashes. Serious side effects include changes in your sight, skin, hair or body temperature and vomiting with blood and/or black stools. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DEFERASIROX-TEVA®

Active ingredient(s): *deferasirox*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DEFERASIROX-TEVA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DEFERASIROX-TEVA.**

Where to find information in this leaflet:

- [1. Why am I using DEFERASIROX-TEVA?](#)
- [2. What should I know before I use DEFERASIROX-TEVA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use DEFERASIROX-TEVA?](#)
- [5. What should I know while using DEFERASIROX-TEVA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using DEFERASIROX-TEVA?

DEFERASIROX-TEVA contains the active ingredient deferasirox. DEFERASIROX-TEVA is used to treat a condition called iron overload, which happens when the body has too much iron. This can occur after repeated blood transfusions. The body has no natural

way to remove excess iron which comes with blood transfusions.

Over time, this excess iron can damage important organs such as the liver and heart. Deferasirox attaches itself to the iron molecules to remove the excess iron from the body. This will help prevent iron induced organ damage.

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

This type of medicine must be taken every day to help remove the excess iron from your body.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use DEFERASIROX-TEVA?

Warnings

Do not use DEFERASIROX-TEVA if:

- you are allergic to deferasirox, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

- the medicine is past the expiry date printed on the pack.
- the packaging is torn or shows signs of tampering. In that case, return it to your pharmacist.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Do not take DEFERASIROX-TEVA if you have any of the following medical conditions:

- severe kidney problems.
- low level of platelets or white blood cell counts.
- an advanced stage of myelodysplastic syndrome (MDS) or advanced cancer.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have a low level of platelets or white blood cells in your blood test
- have any problems with your kidneys or liver

Your doctor may want to take special precautions in this case.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

If you become pregnant while taking this medicine, tell your doctor immediately as DEFERASIROX-TEVA may affect your developing baby.

If you intend to become pregnant while taking this medicine your doctor can discuss with you the risk and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

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.

Some medicines may interfere with DEFERASIROX-TEVA and affect how it works. These include:

- cyclosporin, used in transplantation to prevent organ rejection or to treat rheumatoid arthritis or atopic dermatitis
- midazolam (a medicine used to sedate)

- simvastatin (medicines used to lower cholesterol)
- hormonal contraceptive agents (birth control medicines). Their effectiveness may be reduced while taking DEFERASIROX-TEVA. Use additional contraception.
- certain painkillers or anti-inflammatory medicines (e.g. aspirin, ibuprofen, corticosteroids)
- oral bisphosphonates (medicines used to treat osteoporosis)
- anticoagulant medicines (medicines used to prevent or treat blood clotting)
- antacid preparations containing aluminium, which should not be taken at the same time of day as DEFERASIROX-TEVA
- a medicine for type 2 diabetes called repaglinide
- certain medicines for epilepsy or sedation (phenytoin, phenobarbitone)
- a medicine for HIV called ritonavir
- a medicine for tuberculosis called rifampicin
- a medicine for cancer called paclitaxel
- a medicine used to remove bile acids called cholestyramine
- theophylline (used to treat respiratory diseases such as asthma)
- busulfan (used as treatment prior to bone marrow transplant)

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.

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.

If you have not told your doctor about any of these things, tell him/ her before you start taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DEFERASIROX-TEVA.

4. How do I use DEFERASIROX-TEVA?

How much to take

- the dose of DEFERASIROX-TEVA 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.
- 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.
- follow the instructions provided and use DEFERASIROX-TEVA until your doctor tells you to stop.

When to take DEFERASIROX-TEVA

- DEFERASIROX-TEVA should be taken once a day, every day, at about the same time each day with some water.
- taking DEFERASIROX-TEVA at the same time each day will help you remember when to take your tablets.

Do not stop taking DEFERASIROX-TEVA unless your doctor tells you to - even if you feel well.

This medicine helps to control your condition, but does not cure it. Therefore, you must take it every day. Continue taking the medicine as long as your doctor tells you to.

How to take DEFERASIROX-TEVA

- take the tablets either on an empty stomach or with a light meal.

- the film-coated 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 like yogurt or apple sauce (apple puree). You should then eat it all immediately. Do not keep any to have later.

If you forget to take DEFERASIROX-TEVA

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

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much DEFERASIROX-TEVA

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

5. What should I know while using DEFERASIROX-TEVA?

Things you should do

- if you notice substantially reduced urine output, tell your doctor straight away. This could be a sign of a problem with your kidneys.
- elderly patients should be monitored closely by their doctor. Elderly patients may experience more side effects than younger patients and their doctor may adjust their dose.
- keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do regular tests (blood, urine or Magnetic Resonance Imaging (MRI)) to make sure the medicine is working and to prevent unwanted side effects. Your doctor will also use these tests to decide when you should stop taking DEFERASIROX-TEVA.

Your eyesight and hearing may be tested during treatment as a precautionary measure.

- tell your doctor immediately if you become pregnant while taking DEFERASIROX-TEVA. Your doctor will discuss the risks and benefits of continuing treatment in this case.
- if you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.
- if you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Call your doctor straight away if you:

- develop a rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms and enlarged lymph nodes (signs of severe skin reaction) STOP taking DEFERASIROX-TEVA immediately and tell your doctor straight away.

Remind any doctor, dentist or pharmacist you visit that you are using DEFERASIROX-TEVA.

Things you should not do

- do not stop using this medicine suddenly unless your doctor tells you.
- do not use DEFERASIROX-TEVA to treat any other complaint unless your doctor says so.
- do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- do not stop treatment without first checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DEFERASIROX-TEVA affects you.

DEFERASIROX-TEVA may cause dizziness in some people.

If you experience dizziness, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep your medicine in the original container until it is time to take it.

Store it in a cool dry place below 25°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Elderly patients may experience more side effects than younger patients.

Less serious side effects

Less serious side effects	What to do
<p>Stomach or bowel problems such as:</p> <ul style="list-style-type: none">• pain in the abdomen• nausea• diarrhoea• vomiting• bloating• indigestion• constipation <p>Difficulty thinking or working because of:</p> <ul style="list-style-type: none">• headache• trouble sleeping	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • dizziness <p>Throat or lung infections such as:</p> <ul style="list-style-type: none"> • fever or symptoms of a cold or flu • cough • sore throat <p>Other changes such as:</p> <ul style="list-style-type: none"> • rash • itching • swelling of arms or legs • change in the colour of the skin • feeling sleepy • anxiety • tiredness • sore muscles or joints • hair loss 	

Serious side effects

Serious side effects	What to do
<p>Changes in your sight, namely:</p> <ul style="list-style-type: none"> • blurred or cloudy vision 	<p>Call your doctor straight away, or go straight to the Emergency Department at your</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● partial loss of vision <p>Changes to the skin or hair such as:</p> <ul style="list-style-type: none"> ● swelling of the face, lips, tongue or throat ● signs of severe skin reaction such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms and enlarged lymph nodes ● severe itching of the skin, with a red rash or raised bumps <p>Changes to your excretory and digestive systems:</p> <ul style="list-style-type: none"> ● a substantially reduced urine output ● vomiting with blood and/ or black stools <p>Body temperature changes such as:</p> <ul style="list-style-type: none"> ● fever ● flu-like symptoms 	<p>nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Other side effects such as:</p> <ul style="list-style-type: none"> ● hearing disturbances ● difficulty in breathing and swallowing ● sudden back pain or pain on the right side of the abdomen (signs of gallstones) ● severe upper stomach pain (pancreatitis) ● a tear in stomach or intestine wall that can be painful and cause nausea ● drowsiness, upper right abdominal pain, yellowing of your skin or eyes and dark urine (sign of liver problem) ● frequent heartburn or abdominal pain (ulcers), particularly after eating or taking the drug 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Some of these side effects, for example, changes in kidney and liver function, can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is not addictive.

This medicine is only available with a doctor's prescription.

What DEFERASIROX-TEVA contains

Active ingredient (main ingredient)	Contains either 90, 180 or 360mg of deferasirox
Other ingredients	Crospovidone

(inactive ingredients)

Povidone
Microcrystalline Cellulose
Magnesium stearate
Poloxamer
Colloidal hydrous silica
Coating material
consisting of:
Hypromellose
Titanium dioxide
Macrogol
Talc
Indigo carmine aluminium
lake

Do not take this medicine if you are allergic to any of these ingredients.

What DEFERASIROX-TEVA looks like

The film-coated tablets are provided in blister packs (30 tablets).

DEFERASIROX-TEVA 90 mg: Light blue unscored ovaloid biconvex film-coated tablet with bevelled edges, debossed with '90' on one side and plain on the other side.

DEFERASIROX-TEVA 180 mg: Medium blue unscored ovaloid biconvex film-coated tablet with bevelled edges, debossed with '180' on one side and plain on the other side.

DEFERASIROX-TEVA 360 mg: Dark blue unscored ovaloid biconvex film-coated tablet with bevelled edges, debossed with '360' on one side and plain on the other side

Australian Registration Number:

DEFERASIROX-TEVA 90 mg AUST R 350825

DEFERASIROX-TEVA 180 mg AUST R 350824

DEFERASIROX-TEVA 360 mg AUST R 350822

Who distributes DEFERASIROX-TEVA

DEFERASIROX-TEVA is supplied in Australia by:

Teva Pharma Australia Pty Ltd
Level 1, 37 Epping Road
Macquarie Park NSW 2113
Australia

1800 288 382

www.tevapharma.com.au

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