

# JEDOXRED 125 (Deferasirox Dispersible Tablets 125mg)

# JEDOXRED 250 (Deferasirox Dispersible Tablets 250mg)

# JEDOXRED 500 (Deferasirox Dispersible Tablets 500mg)

Deferasirox Dispersible Tablets 125mg, 250mg, 500mg

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**What Jedoxred is used for**

Jedoxred is used to treat chronic iron overload in:

- adult patients and children aged 2 years and older who receive blood transfusions for the treatment of anemias;
- adult patients and children aged 10 years and older with thalassemia syndromes who do not require regular blood transfusions for the treatment of anemia.

**How Jedoxred works**

Jedoxred is an iron chelating agent which removes the excess iron from the body (also called iron overload), thereby reducing the risk of organ damage caused by iron overload.

**Before you use Jedoxred**- When you must not use it

- If you are allergic (hypersensitive) to deferasirox or any of the other

ingredients (in particular, lactose) of Jedoxred listed in the section "Product Description".

- If you have severe kidney disease.

- If you have an advanced stage of myelodysplastic syndrome (MDS) or advanced cancer.
- If you have low platelet count (<50 x 10<sup>9</sup>/L).

Pregnancy and lactation

Jedoxred is not recommended during pregnancy unless clearly necessary. If you are pregnant or think that you may be, tell your doctor. Jedoxred may decrease the effect of hormonal contraceptives, and you may be at risk of getting pregnant if you are taking a hormonal contraceptive. Breast-feeding is not recommended during treatment with Jedoxred.

- Before you start to use it

Talk to your doctor or pharmacist if you have:

- severe heart problems (acute cardiac failure).
- ulcer or bleeding in the stomach or intestines.
- liver or kidney problems.
- severe intolerance to lactose (milk sugars). Jedoxred tablets contain lactose.
- visual (eye) problems.
- hearing problems.
- blood disorders (a low level of platelets or white blood cell count).
- skin problem.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently

taken any other medicines, including non-prescription drugs (obtained without a prescription), vitamins and

natural products. Some medicines may interact with Jedoxred:

- Antacids (medicines used to treat heartburn) containing aluminum should not be taken at the same time of day as Jedoxred.

In particular tell your doctor if you are taking any of the following:

- cyclosporine (used in transplantation to prevent graft rejection or for any other condition)
- simvastatin (used to lower cholesterol)
- hormonal contraceptive agents (birth control medicines)
- certain painkillers or anti-inflammatory medicines (e.g. acetylsalicylic acid, ibuprofen, corticosteroids)
- oral bisphosphonates (used to treat osteoporosis)
- anticoagulant medicines (used to prevent or treat blood clotting)
- repaglinide (used to treat diabetes)
- rifampicin (used to treat tuberculosis)
- paclitaxel (used in cancer treatment)
- phenytoin, phenobarbital (used to treat epilepsy)
- ritonavir (used in the treatment of HIV infection)
- cholestyramine (used mainly to lower cholesterol)
- theophylline (used to treat respiratory diseases such as asthma)
- busulfan (used as treatment prior to bone marrow transplant)

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## How to use Jedoxred

### - How much to use

Always take Jedoxred exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Usual dose:

For patients receiving regular blood transfusion:

- Initial dose: 10 mg, or 20 mg, or 30 mg per kg body weight daily.
- Maximum dose: 40 mg per kg body weight daily.

For patients with thalassemia syndromes who do not require regular blood transfusions:

- Initial dose: 10 mg per kg body weight daily.
- Maximum dose: 20 mg per kg body weight daily.

The daily dose will be adjusted depending on how you respond to the treatment.

Jedoxred dispersible tablets are dispersed by stirring in a glass of water or orange or apple juice (100 to 200 ml) until a fine suspension is obtained. After the suspension has been swallowed, any residue must be re-suspended in a small volume of water or juice and swallowed. Dispersion in carbonated drinks or milk is not recommended due to foaming and slow dispersion, respectively. The tablets must not be chewed or swallowed whole.

### - When to use it

- Take Jedoxred once a day, every day, at about the same time each day;

- Must be taken on an empty stomach;
- Then wait at least 30 minutes before eating the first meal of the day.

### - How long to use it

Continue using Jedoxred for as long as your doctor recommends.

### - If you forget to use it

If you miss a dose, take it as soon as you remember on that day. Take your next dose as scheduled. Do not take a double dose on the next day to make up for the forgotten dose. Do not take more than one dose on the same day.

### - If you use too much (overdose)

If you have taken too much Jedoxred, or if someone else accidentally takes your tablets, contact your doctor or go to the hospital or contact your local poison control centre. Show them the blister package of tablets. Medical treatment may be necessary.

## While you are using it

### - Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking Jedoxred.

Tell your doctor immediately if you become pregnant while taking this medication.

During treatment with Jedoxred, talk to your doctor or pharmacist immediately if you have:

- Rash, red skin, pain, swelling or blistering of the lips, eyes or mouth,

skin peeling, high fever and flu-like symptoms and swollen lymph glands. If you get these symptoms, your doctor may stop your treatment

You should receive regular blood and urine tests before and during treatment with Jedoxred. You may also be assessed by Magnetic Resonance Imaging (MRI). These will monitor the amount of iron in your body (level of ferritin) to see how well Jedoxred is working. The tests will also monitor your kidney function (blood level of creatinine, presence of protein in the urine) and liver function (blood level of transaminases, bilirubin and alkaline phosphatase). Your doctor will take these tests into consideration when deciding on the dose of Jedoxred most suitable for you and will also use these tests to decide when you should stop taking Jedoxred. Your eyesight and hearing will also be tested before and periodically during treatment as a precautionary measure. The safety of Jedoxred when administered with other iron chelation therapy has not been established.

### - Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Jedoxred to anyone else, even if they have the same symptoms or condition as you.

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## - Things to be careful of

*Older people (age 65 years and over):* Elderly patients may experience more side effects than younger patients. They should be monitored closely by their doctor for side effects that may require a dose adjustment.

*Children and adolescents (age 2 years to 16 years):* Their growth and development need to be monitored during treatment with Jedoxred

## *Driving and using machines*

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

## **Side effects**

Like all medicines, Jedoxred can cause side effects. Some side effects are common.

- Gastrointestinal disorders, such as nausea, vomiting, diarrhea, pain in the abdomen, bloating, constipation, indigestion
- Skin rash
- Headache

Other side effects are uncommon.

- Dizziness
- Fever
- Sore throat
- Swelling of arms or legs
- Change in the colour of the skin
- Anxiety
- Sleep disorder
- Tiredness

- Hearing loss
- Vision change (early cataracts)
- Ulcer and/or bleeding in the stomach or intestine
- Liver disorders
- Traces of blood and/or protein in the urine
- Hair loss

You will have some blood tests while taking Jedoxred. Your doctor will look for any changes in kidney function, liver function, or in blood cell counts. Your doctor may also want to test your eyesight and hearing while you are taking Jedoxred. You may notice other side effects not listed in this leaflet. If you are concerned with any side effect, or if any side effect makes you feel unwell, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## **Storage and Disposal of Jedoxred**

### - Storage

Keep out of the reach and sight of children. Store below 30°C.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **Product Description**

### - What it looks like

Jedoxred 125: White to off-white, round, flat, uncoated size 10mm tablets, with debossing 'D' on one side and '125' on other side.

Jedoxred 250: White to off-white, round, flat, uncoated size 12mm tablets, with debossing 'D' on one side and '250' on other side.

Jedoxred 500: White to off-white, round, flat, uncoated size 16mm tablets, with debossing 'D' on one side and '500' on other side.

### - Ingredients

- Active ingredient: Deferasirox

- Inactive ingredients: Cellulose Microcrystalline, Crospovidone, Sodium Lauryl Sulphate, Povidone K30, Microcrystalline Cellulose, Lactose monohydrate, Croscarmellose sodium, Colloidal silicon dioxide, Magnesium stearate

### - MAL number:

Jedoxred 125: MAL20046127AZ

Jedoxred 250: MAL20046128AZ

Jedoxred 500: MAL20046129AZ

## **Manufacturer**

MSN Laboratories Private Limited  
Formulation Division, Unit-II,  
Sy.No. 1277 & 1319 to 1324,  
Nandigama (Village & Mandal)  
Rangareddy District-509228,  
Telangana, India.

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**Product Registration Holder**

Dr. Reddy's Laboratories Malaysia

Sdn. Bhd.

UNIT NO. SO-29-07 AND

SO-29-08, MENARA 1,

STRATA OFFICE, NO. 3,

JALAN BANGSAR, KL ECO

CITY, 59200 KUALA LUMPUR

MALAYSIA

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