DEFRIJET

Deferasirox Dispersible Tablets (125mg, 250mg, 500mg)

What is in this leaflet

What DEFRIJET is used for

DEFRIJET 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 DEFRIJET works

DEFRIJETis 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 DEFRIJET

- *When you must not use it*

- If you are allergic (hypersensitive) to deferasirox or any of the other ingredients (in particular, lactose) of **DEFRIJET** 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 10^9/L).

Pregnancy and lactation

DEFRIJET is not recommended during pregnancy unless clearly necessary. If you are pregnant or think that you may be, tell your doctor. **DEFRIJET** 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 **DEFRIJET**.

- *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). **DEFRIJET** tablets contain lactose.
- visual (eye) problems.
- hearing problems.
- blood disorders (a low level of platelets or white blood cell count).
- skin problem.

DEFRIJET contains less than 1 mmol sodium (23mg) per dispersible tablet that is to say essentially 'sodium free'.

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

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)

How to use DEFRIJET

- *How much to use*

Always take **DEFRIJET** 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.

DEFRIJET 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 **DEFRIJET** 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 **DEFRIJET** 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 take more **DEFRIJET** 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 DEFRIJET

- *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 **DEFRIJET**.

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

During treatment with **DEFRIJET**, 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 **DEFRIJET**. 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 **DEFRIJET** 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 **DEFRIJET** most suitable for you and will also use these tests to decide when you should stop taking **DEFRIJET**.

Your eyesight and hearing will also be tested before and periodically during treatment as a precautionary measure. The safety of **DEFRIJET** 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.

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

- *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 **DEFRIJET.**

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, **DEFRIJET** can cause side effects, although not everybody gets them. 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 **DEFRIJET**. 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 **DEFRIJET**. 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 you doctor or pharmacist.

Reporting of side effects

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 [Consumers →Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of DEFRIJET TABLETS

DEFRIJET is available as triplex blister pack of 10 tablets. Such 3 blisters are packed in Show box/carton along with Pack Insert.

- *Storage*

Store below 30°C. Store in the original package in order to protect from

moisture.

- *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*

DEFRIJET 125 mg
Off - white, round uncoated tablets, flat with beveled edges, debossed with '568' on one side and plain on the other side

DEFRIJET 250 mg
Off - white, round uncoated tablets, flat with beveled edges, debossed with '569' on one side and plain on the other side.

DEFRIJET 500 mg
Off - white, round uncoated tablets, flat with beveled edges, debossed with '570' on one side and plain on the other side.

- *Ingredients:*
- Active ingredient(s): Deferasirox

- Inactive ingredients: Lactose monohydrate, Crospovidone, Colloidal silicon dioxide, Povidone, Sodium lauryl Sulphate, purified water, microcrystalline cellulose, magnesium stearate

- *MAL number:*
125mg MAL NO: MALXXXXXXX
250mg MAL NO: MALXXXXXXX
500mg MAL No.:MALXXXXXXX

Manufactured by:
Sun Pharmaceutical Industries Limited
Survey No. 1012, Dadra
Union Territory Of Dadra & Nagar Haveli and Daman and Diu, IN-396193, India

Product Registration Holder
RANBAXY (MALAYSIA) SDN. BHD.
Lot 23, Bakar Arang Industrial Estate, 08000 Sungai Petani, Kedah, MALAYSIA

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