DEFRATAJ

500MG, 250MG

(DEFERASIROX)

Package leaflet:

Information for the patient
DEFRATAJ 500 mg film-coated tablets
DEFRATAJ 250 mg film-coated tablets
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet

1.WHAT DEFRATAJ IS AND WHAT IT IS USED FOR

What DEFRATAJ is
DEFRATAJ contains an active substance called deferasirox. It is an iron chelator which is a medicine used to remove the excess iron from the body (also called iron overload). It traps and removes excess iron which is then excreted mainly in the stools.

What DEFRATAJ is used for
Repeated blood transfusions may be necessary in patients with various types of anaemia (for example thalassaemia, sickle cell disease or myelodysplastic syndromes (MDS)). However, repeated blood transfusions can cause a build-up of excess iron. This is because blood contains iron and your body does not have a natural way to remove the excess iron you get with your blood transfusions. In patients with non-transfusion-dependent thalassaemia syndromes, iron overload may also develop over time, mainly due to increased absorption of dietary iron in response to low blood cell counts. Over time, the excess iron can damage important organs such as the liver and heart. Medicines called iron chelators are used to remove the excess iron and reduce the risk of it causing organ damage. DEFRATAJ is used to treat chronic iron overload caused by frequent blood transfusions in patients with beta thalassaemia major aged 6 years and older.

DEFRATAJ is also used to treat chronic iron overload when deferoxamine therapy is contraindicated or inadequate in patients with beta thalassaemia major with iron overload caused by infrequent blood transfusions, in patients with other types of anaemias, and in children aged 2 to 5 years.

DEFRATAJ is also used when deferoxamine therapy is contraindicated or inadequate to treat patients aged 10 years or older who have iron overload associated with their thalassaemia syndromes, but who are not transfusion dependent.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DEFRATAJ

Do not take DEFRATAJ Capsules:
- if you are allergic to deferasirox or any of the other ingredients of this medicine (listed in section 6). If this applies to you, tell your doctor before taking DEFRATAJ. If you think you may be allergic, ask your doctor for advice.
- if you have moderate or severe kidney disease.
- if you are currently taking any other iron chelator medicines.

DEFRATAJ is not recommended
- if you are at an advanced stage of myelodysplastic syndrome (MDS; decreased production of blood cells by the bone marrow) or have advanced cancer.

Warnings and precautions
Talk to your doctor or pharmacist before taking DEFRATAJ:
- if you have a kidney or liver problem.
- if you have a cardiac problem due to iron overload.
- if you notice a marked decrease in your urine output (sign of kidney problem).
- if you develop a severe rash, or difficulty breathing and dizziness or swelling mainly of the face and throat (signs of severe allergic reaction, see also section 4 “Possible side effects”).
- if you experience a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms, enlarged lymph nodes (signs of severe skin reaction, see also section 4 “Possible side effects”).
- if you experience a combination of drowsiness, upper right abdominal pain, yellowing or increased yellowing of your skin or eyes and dark urine (signs of liver problems).
- if you experience difficulty thinking, remembering information, or solving problems, being less alert or aware or feeling very sleepy with low energy (signs of a high level of ammonia in your blood, which may be associated with liver or renal problems, see also section 4 “Possible side effects”).
- if you vomit blood and/or have black stools.
- if you experience frequent abdominal pain, particularly after eating or taking DEFRATAJ.
- if you experience frequent heartburn.
- if you have a low level of platelets or white blood cells in your blood test.
- if you have blurred vision
- if you have diarrhoea or vomiting.

If any of these apply to you, tell your doctor straight away.

Monitoring your DEFRATAJ treatment You will have regular blood and urine tests during treatment. These will monitor the amount of iron in your body (blood level of ferritin) to see how well DEFRATAJ 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). Your doctor may require you to undergo a kidney biopsy, if he/she suspects significant kidney damage.

You may also have MRI (magnetic resonance imaging) tests to determine the amount of iron in your liver. Your doctor will take these tests into consideration when deciding on the dose of DEFRATAJ most suitable for you and will also use these tests to decide when you should stop taking DEFRATAJ.

Your eyesight and hearing will be tested each year during treatment as a precautionary measure.

Other medicines and DEFRATAJ

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes in particular:
- other iron chelators, which must not be taken with DEFRATAJ,
- antacids (medicines used to treat heartburn) containing aluminium, which should not be taken at the same time of day as DEFRATAJ,
- ciclosporin (used to prevent the body rejecting a transplanted organ or for other conditions, such as rheumatoid arthritis or atopic dermatitis),
- 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),
- bepridil, ergotamine (used for heart problems and migraines),
- repaglinide (used to treat diabetes),
- rifampicin (used to treat tuberculosis),
- phenytoin, phenobarbital, 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 (used to lower cholesterol levels in the blood),
- busulfan (used as a treatment prior to transplantation in order to destroy the original bone marrow before the transplant).

Additional tests may be required to monitor the blood levels of some of these medicines.

Older people (age 65 years and over)
DEFRATAJ can be used by people aged 65 years and over at the same dose as for other adults. Elderly patients may experience more side effects (in particular diarrhoea) than younger patients. They should be monitored closely by their doctor for side effects that may require a dose adjustment.

Children and adolescents DEFRATAJ can be used in children and adolescents receiving regular blood transfusions aged 2 years and over and in children and adolescents not receiving regular blood transfusions aged 10 years and over. As the patient grows the doctor will adjust the dose.

DEFRATAJ is not recommended for children aged under 2 years.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

DEFRATAJ is not recommended during pregnancy unless clearly necessary.

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 DEFRATAJ may reduce the effectiveness of oral and patch contraceptives.

Breast-feeding is not recommended during treatment with DEFRATAJ.

Driving and using machines
If you feel dizzy after taking DEFRATAJ, do not

drive or operate any tools or machines until you are feeling normal again.

3. HOW TO TAKE DEFRATAJ

Treatment with DEFRATAJ will be overseen by a doctor who is experienced in the treatment of iron overload caused by blood transfusions.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much DEFRATAJ to take
The dose of DEFRATAJ 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 daily dose for DEFRATAJ film-coated tablets at the start of the treatment for patients receiving regular blood transfusions is 14 mg per kilogram body weight. A higher or lower starting dose may be recommended by your doctor based on your individual treatment needs.
 The usual daily dose for DEFRATAJ film-coated tablets at the start of the treatment for patients notreceiving regular blood transfusions is 7 mg per kilogram body weight.
 Depending on how you respond to treatment, your doctor may later adjust your treatment to a higher or lower dose.

 The maximum recommended daily dose for DEFRATAJ film-coated tablets is:

 28 mg per kilogram body weight for patients receiving regular blood transfusions,
 14 mg per kilogram body weight for adult patients not receiving regular blood transfusions,
 7 mg per kilogram body weight for children and adolescents not receiving regular blood transfusions.

Deferasirox also comes as “dispersible” tablets. If you are switching from the dispersible tablets to these film-coated tablets, you will need an adjustment of the dose.

When to take DEFRATAJ
 Take DEFRATAJ once a day, every day, at about the same time each day with some water.
 Take DEFRATAJ film-coated tablets either on an empty stomach or with a light meal. Taking DEFRATAJ at the same time each day will also help you remember when to take your tablets.

For patients who are unable to swallow whole tablets, DEFRATAJ film-coated tablets may be crushed and taken by sprinkling the full dose onto soft food such as yogurt or apple sauce (pureed apple). The food should be immediately and completely consumed. Do not store it for future use.

How long to take DEFRATAJ
Continue taking DEFRATAJ every day for as long as your doctor tells you.
This is a long-term treatment, possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect (see also section 2: “Monitoring your DEFRATAJ treatment”).

If you have questions about how long to take DEFRATAJ, talk to your doctor.
If you take more DEFRATAJ than you should

If you have taken too much DEFRATAJ, or if someone else accidentally takes your tablets, contact your doctor or hospital for advice straight away. Show them the pack of tablets. Medical treatment may be necessary.

If you forget to take DEFRATAJ
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 tablet(s).

If you stop taking DEFRATAJ
Do not stop taking DEFRATAJ unless your doctor tells you to. If you stop taking it, the excess iron will no longer be removed from your body (see also above section "How long to take DEFRATAJ").

4.POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment.
Some side effects could be serious and need immediate medical attention.
These side effects are uncommon (may affect up to 1 in 100 people) or rare (may affect up to 1 in 1,000 people).
- If you get a severe rash, or difficulty breathing and dizziness or swelling mainly of the face andthroat (signs of severe allergic reaction),
- If you experience a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, high fever, flu-like symptoms, enlarged lymph nodes, (signs of severe skin reactions),
- If you notice a marked decrease in your urine output (sign of kidney problem),
- If you experience a combination of drowsiness, upper right abdominal pain, yellowing or increased yellowing of your skin or eyes and dark urine (signs of liver problems),
- If you experience difficulty thinking, remembering information, or solving problems, being less alert or aware or feeling very sleepy with low energy (signs of a high level of ammonia in your blood, which may be associated with liver or renal problems and lead to a change in your brain function),
- If you vomit blood and/or have black stools,
- If you experience frequent abdominal pain, particularly after eating or taking DEFRATAJ,
- If you experience frequent heartburn,
- If you experience partial loss of vision,
- If you experience severe upper stomach pain (pancreatitis),

stop taking this medicine and tell your doctor straight away.

Some side effects could become serious.
These side effects are uncommon.
- If you get blurred or cloudy eyesight,
- If you get reduced hearing,

tell your doctor as soon as possible.

Other side effects
Very common (may affect more than 1 in 10 people)
- Disturbance in kidney function tests.

Common (may affect up to 1 in 10 people)
- Gastrointestinal disorders, such as nausea, vomiting, diarrhoea, pain in the abdomen, bloating, constipation, indigestion
- Rash
- Headache
- Disturbance in liver function tests
- Itching
- Disturbance in urine test (protein in the urine) If any of these affects you severely, tell your doctor.

Uncommon (may affect up to 1 in 100 people) • Dizziness

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

If any of these affects you severely, tell your doctor.

Frequency not known (cannot be estimated from the available data).

- A decrease in the number of cells involved in blood clotting (thrombocytopenia), in the number of red blood cells (anaemia aggravated), in the number of white blood cells (neutropenia) or in the number of all kinds of blood cells (pancytopenia)
- Hair loss
- Kidney stones
- Low urine output
- Tear in stomach or intestine wall that can be painful and cause nausea
- Severe upper stomach pain (pancreatitis)
- Abnormal level of acid in blood

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland	HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie
Malta	ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal
United Kingdom	Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5.HOW TO STORE DEFRATAJ

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.
- Do not use any pack that is damaged or shows signs of tampering.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND FURTHER INFORMATION

What DEFRATAJ contains

The active substance is deferasirox.

- Each film-coated tablet of DEFRATAJ 500 mg contains 500 mg deferasirox.
- Each film-coated tablet of DEFRATAJ 250 mg contains 250 mg deferasirox

The other ingredients are microcrystalline cellulose; crospovidone; povidone; magnesium stearate; colloidal anhydrous silica and poloxamer. The tablet coating material contains: hypromellose; titanium dioxide (E171); macrogol (4000); talc; indigo carmine aluminium lake (E132).

What DEFRATAJ looks like and contents of the pack

DEFRATAJ is supplied as film-coated tablets. The film-coated tablets are ovaloid and biconvex.

- DEFRATAJ 500 mg film-coated tablets are medium blue and stamped “500” on one side and “NVR” on the other.
- DEFRATAJ 250 mg film-coated tablets are dark blue and stamped “250” on one side and “NVR” on the other.

Each blister pack contains 30 or 90 film-coated tablets. The multipacks contain 300 (10 packs of 30) film-coated tablets.

Not all pack sizes or strengths may be available in your country.

Manufactured by:
Taj Pharmaceuticals Limited
220, Mahagujarat Ind. Estate, Moraiya, Tal. Sanand, Dist. Ahmedabad, Gujarat, INDIA

Marketing Authorization Holder:
Regal sun co., Ltd.Myanmar