NOVARTIS

Exjade® (deferasirox)

125 mg, 250 mg and 500 mg dispersible tablet

Patient Information Leaflet

Document status: Final

Approval date: 15 April 2020

SCHEDULING STATUS: S4

PRODUCT NAME

EXJADE 250 mg dispersible tablets

EXJADE 500 mg dispersible tablets

Deferasirox

Read all of this leaflet carefully before you start taking EXJADE

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor, pharmacist, nurse or other health care providers**
- **EXJADE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

What is in this leaflet

1. What EXJADE is and what it is used for
2. What you need to know before you take EXJADE
3. How to take EXJADE
4. Possible side effects
5. How to store EXJADE
6. Contents of the pack and other information

1. WHAT EXJADE IS AND WHAT IT IS USED FOR

The active ingredient of EXJADE 250 mg dispersible tablets is 250 mg deferasirox. The active ingredient of EXJADE 500 mg dispersible tablets is 500 mg deferasirox.

EXJADE contains an active substance called deferasirox an iron chelator used to remove the excess iron from the body tissues.

EXJADE is used for:

- Transfusional iron overload (excess amount of iron in patients receiving regular blood transfusions) EXJADE is used to treat iron overload caused by blood transfusions.
- Non-transfusion-dependent thalassaemia syndromes (excess amount of iron in patients with thalassaemia not receiving regular blood transfusions).

2. What you need to know before you take EXJADE

Follow all the doctor's instructions carefully. The instructions may differ from the general information contained in this leaflet.

Do not take EXJADE

- If you are hypersensitive (allergic) to deferasirox or any of the other ingredients of EXJADE (listed in section 6).
- If you have any kidney problem.
- If you have high risk myelodysplastic syndrome (MDS).
- If you have other blood disorders.
- If you have severe liver disease
- If you are pregnant

If this applies to you, tell your doctor before taking EXJADE. If you think you may be allergic, ask your doctor for advice.

Warnings and precautions

Take special care with EXJADE

If any of the following apply to you, tell your doctor or pharmacist or healthcare provider before taking EXJADE:

- If you have a mild to moderate liver problem.
- If you have severe inherited intolerance to milk sugars (e.g. lactose) as EXJADE tablets contain lactose.
- If you are taking anti-inflammatory medication (NSAIDs) as it may increase the risk of gastrointestinal complications.
- Extra caution should be used in elderly patients as they may experience side effects more frequently.
- Blood tests to monitor the amount of ferritin should be done regularly.

Taking EXJADE with food and drink

EXJADE must be taken on an empty stomach at least 30 minutes before eating any food preferably at the same time each day. EXJADE tablets must be dispersed in water, apple or orange juice. For more information, see section 3 “How to take EXJADE”.

Do not dissolve tablets in fizzy drinks or milk.

Pregnancy, Breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking EXJADE

The effect of EXJADE on human fertility is not known

Pregnancy

EXJADE is not to be used during pregnancy. If you are pregnant or think you may be, tell your doctor before taking EXJADE. Your doctor will discuss with you the potential risk of taking EXJADE during pregnancy.

Breastfeeding mothers

Breastfeeding is not recommended during treatment with EXJADE. Tell your doctor if you are breastfeeding your infant

Driving and using machines

If you feel dizzy after taking EXJADE, do not drive or operate any tools or machines until you are feeling normal again.

Other medicines and EXJADE

- If you are taking medicines on a regular basis, including complementary or traditional medicines, the concomitant use of EXJADE may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.
- Antacids (medicines used to treat heartburn) containing aluminium should not be taken at the same time as EXJADE.
- Anti-inflammatory (NSAIDs) medication may increase the risk of gastrointestinal complications.
- theophylline (used to treat respiratory diseases such as asthma).

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.

3. How to take EXJADE

Always take EXJADE exactly as your doctor has told you. Check with your doctor or pharmacist or healthcare provider if you are not sure.

How much EXJADE to take

- EXJADE can be used to treat adults, adolescents and children aged 6 years and over. The dose of EXJADE is related to body weight for all patients. Your doctor will tell you how many tablets to take.
- The usual daily dose of EXJADE at the start of the treatment is 20 mg per kilogram body weight for patients receiving regular blood transfusions
- **10** mg per kilogram body weight for patients not receiving regular blood transfusions
- A higher or lower starting dose may be recommended by your doctor based on your individual treatment needs. 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 is:
  - **40** mg per kilogram body weight for patients receiving regular blood transfusions
  - **20** mg per kilogram body weight for patients not receiving regular blood transfusions

Take EXJADE

- Once a day, every day, at about the same time each day,
- On an empty stomach at least 30 minutes before eating any food.
- Disperse the tablets completely by stirring in a glass of water, apple or orange juice until a suspension forms. Drink the entire contents of the glass, then add a little water or juice to what is left in the empty glass and drink that too.



How long to take EXJADE

It is important to take EXJADE every day and continue your treatment exactly as prescribed. Your doctor will regularly monitor your condition to check that EXJADE is having the desired effect.

If you take more EXJADE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Show the doctor the pack of tablets/granules. Urgent medical treatment may be necessary. You may experience effects such as abdominal pain, diarrhea, nausea and vomiting, and kidney or liver problems that can be serious.

If you forget to take EXJADE

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.

If you stop taking EXJADE

Do not stop taking EXJADE unless your doctor tells you to. If you stop taking EXJADE, the excess iron will no longer be removed from your body.

4. POSSIBLE SIDE EFFECTS

EXJADE can have side effects.

Not all side effects reported for EXJADE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EXJADE, please consult your provider for advice.

If you experience any of these serious side effects, stop taking EXJADE and tell your doctor immediately.

Frequent:

- If you notice a severely decreased 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 vomit blood and/or have black stools,
- If you experience frequent abdominal pain (ulcers) particularly after eating or taking EXJADE,
- If you experience frequent heartburn,
- If you experience partial loss of vision
- Rash, skin reddening, blistering of lips, eyes or mouth , skin peeling, sore throat (signs of severe skin reaction), Steven Johnson Syndrome.
- Skin rashes may appear during treatment.
- Hypersensitivity reactions such as angioedema and anaphylaxis may occur during treatment.
- Vision and hearing may be impaired.
- Blood disorders may arise;

Less frequent:

If the following side effects affect you severely, tell your doctor:

- Dizziness

- Fever
- Blurred or cloudy vision
- Hearing disturbances
- Sore throat
- Swelling of arms or legs
- Change in the colour of the skin
- Anxiety
- Sleep disorder
- Tiredness

You will have some blood tests while taking EXJADE. Your doctor will look for any changes in the kidney function (level of *creatinine*) or liver function (level of *transaminases*).

Your doctor may also want to test your eye sight and hearing while you are taking EXJADE

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store EXJADE

- Do not use after the expiry date stated on the carton.
- Store below 30 °C.
- Store in the original package in order to protect from moisture.
- Do not store EXJADE in the bathroom.
- Keep out of the reach and sight of children.
- Do not use any EXJADE pack that is damaged or shows signs of tampering.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

EXJADE 250/500 mg dispersible tablets contain 250/500 mg of active ingredient deferasirox respectively.

The other inactive ingredients are lactose, crospovidone, povidone, sodium lauryl sulphate, microcrystalline cellulose, silicon dioxide and magnesium stearate.

EXJADE comes in packs of 28 or 84 dispersible tablets in blisters composed of a colourless, transparent PVC/PE/PVDC (polyvinylchloride / polyethylene / polyvinylidene chloride) film with an aluminium foil backing, or a PA/Al/PVC (polyamide / aluminium / polyvinylchloride) film with an aluminium foil backing.

IDENTIFICATION OF EXJADE

EXJADE 250 mg*:* Off-white, round, flat, bevelled edge tablet, with "J250" imprinted on the one side and "NVR" on the other.

EXJADE 500 mg: Off-white, round, flat, bevelled edge tablet, with "J500" imprinted on the one side and "NVR" on the other.

HOLDER OF CERTIFICATE OF REGISTRATION:

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg

2090

This leaflet was last revised in:

15 April 2020

Registration number:

EXJADE 250 mg: A40/27/0267

EXJADE 500 mg: A40/27/0268

2019-PSB/GLC-1065-s, 2018-PSB/GLC-0934-s, 2017-PSB/GLC-0882-s, 2015-PSB/GLC-0763-s,

2014-PSB/GLC-0698-s,

Exjade 250 mg:	
Namibia: 08/27/0123	NS2
Exjade 500 mg:	
Namibia: 08/27/0124	NS2