PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Evrenzo 20 mg film-coated tablets

Evrenzo 50 mg film-coated tablets

Evrenzo 70 mg film-coated tablets

Evrenzo 100 mg film-coated tablets

Evrenzo 150 mg film-coated tablets

Roxadustat

Contains lactose monohydrate (sugar)

Read all of this leaflet carefully before you start taking Evrenzo

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Evrenzo 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 Evrenzo is and what it is used for
2. What you need to know before you take Evrenzo

3. How to take Evrenzo
4. Possible side effects
5. How to store Evrenzo
6. Contents of the pack and other information

1. What Evrenzo is and what it is used for

What Evrenzo is

Evrenzo belongs to a class of medicines that increases the number of red blood cells and haemoglobin level in your blood. It contains the active substance roxadustat.

What Evrenzo is used for

Evrenzo is used to treat anaemia in adults with chronic kidney disease. Anaemia is when you have too few red blood cells and your haemoglobin level is too low. As a result your body tissues might not receive enough oxygen. Anaemia may be associated with symptoms such as tiredness, weakness and shortness of breath.

How Evrenzo works

Roxadustat increases the production of red blood cells and increases haemoglobin level, which improves the oxygen supply to your body and may provide relief to your symptoms.

2. What you need to know before you take Evrenzo

Do not take Evrenzo

- if you are allergic to roxadustat, or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant, think you may be pregnant, or are planning to have a baby.
- if you are breast-feeding.

  Do not give Evrenzo to children or adolescents under 18 years because it is not known whether it is safe and effective in this age group.

Warnings and precautions

Talk to your doctor, or pharmacist before taking Evrenzo:

- if you have epilepsy, or have a history of convulsions, or fits (see section 4 – Possible side effects).
- if you have signs and symptoms of an infection, which may include fever, sweating or chills, sore throat, runny nose, shortness of breath, feeling weak, confusion, cough, vomiting, diarrhoea or stomach pain, burning when you urinate, red or painful skin or sores on your body.
- if you have a liver disorder.

Talk to your doctor, or pharmacist straight away:

- if you experience signs and symptoms of blood clots in your haemodialysis access (vascular access thrombosis or VAT) that causes the vascular access to stop working; this may include swelling, redness, hardening or thickening of the skin around your access,

oozing at the access site, not feeling a vibration (“thrill”) over the access area (see section 4 – Possible side effects).

- if you experience seizures or possible warning signs that a seizure (convulsions or fits) may occur, such as headache, irritability, fear, confusion or unusual feelings (see section 4 – Possible side effects).
- if you have signs and symptoms of an infection, which may include fever, sweating or chills, sore throat, runny nose, shortness of breath, feeling weak, confusion, cough, vomiting, or stomach pain, burning when you urinate, red or painful skin or sores on your body.
- if you experience signs and symptoms of blood clots in the veins of your legs (deep vein thrombosis or DVT), which may include pain and/or swelling in the legs, cramping, a cool or pale leg, a feeling of warmth in the affected leg (see section 4 – Possible side effects).

Children and adolescents

Do not give Evrenzo to children and adolescents under 18 years because it is not known whether it is safe and effective in this age group.

Other medicines and Evrenzo

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular tell your doctor or pharmacist if you have, or are taking any of the following medicines:

- medicines used to lower cholesterol, such as simvastatin, atorvastatin, or rosuvastatin (also called “statins”), or gemfibrozil;
- probenecid, a medicine to treat gout.

If you normally take any of these medicines, your doctor might change it and prescribe a different medicine for you during your treatment with Evrenzo:

- medicines to reduce phosphate levels in your blood (called phosphate binders) or other medicines or supplements that contain calcium, iron, magnesium or aluminium (called multivalent cations).

You must take these medicines or supplements at least 1 hour before you take Evrenzo, or 1 hour after you have taken Evrenzo (see section 3). Otherwise roxadustat will not be properly absorbed by your body.

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 health care provider for advice before taking this medicine.

Evrenzo may harm your unborn baby and should not be used during pregnancy. Women taking Evrenzo who are able to become pregnant should use an effective method of contraception for at least one week prior to start with Evrenzo and until after the last dose of Evrenzo is taken. If you use a hormonal contraceptive, you must also use a barrier method, such as a condom, or a diaphragm.

Do not breastfeed if you are on treatment with Evrenzo.

Driving and using machines

This medicine has minimal effect on your ability to drive or use machines. However, it can cause seizures and dizziness. Therefore, you should not drive or operate machinery when using Evrenzo.

Evrenzo contains a sugar (lactose)

Evrenzo contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product (see section 2).

Evrenzo contains an azo colouring agent (Allura Red AC aluminium lake)

Azo colouring agents may cause allergic reactions. If you are allergic to azo colouring agents talk to your doctor to determine whether you should use this medicine (see section 2).

3. How to take Evrenzo

Leave the blisters in the carton until required for use.

Do not share medicines prescribed for you with any other person.

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

Evrenzo is taken by mouth as tablets.

Your doctor will tell you what dose of Evrenzo to take.

Your prescribed dose can range from 20 mg three times per week up to a maximum 400 mg three times per week. Your dose of Evrenzo maybe a combination of more than one tablet of the same strength, or of different strengths.

Your doctor will check your haemoglobin levels regularly. Your doctor may decide to increase or lower your Evrenzo dose based on your haemoglobin levels.

Taking Evrenzo

- Take your Evrenzo dose three times per week at the same time each day
- Take Evrenzo on the same three days every week
- Do not take Evrenzo on consecutive days
- Leave 1 or 2 days between taking the doses
- Evrenzo can be taken with or without food
- Swallow the tablets whole
- Do not chew, break or crush the tablets

Medicines that reduce phosphate levels in your blood (called phosphate binders) or other medicines or supplements that contain calcium, iron, magnesium or aluminium (called multivalent cations) should be at least 1 hour before you take Evrenzo, or 1 hour after you have taken Evrenzo (see section 3). Otherwise roxadustat will not be properly absorbed by your body.

If you take more Evrenzo than you should

If you take more tablets or a higher dose than you should, contact your doctor straight away.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Evrenzo

If you forget to take your Evrenzo dose at the usual time, take the missed dose as soon as possible. If one day or less remains before the next scheduled dose, skip the missed dose and take the next dose on the next scheduled day.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking Evrenzo

Do not stop taking this medicine unless your doctor tells you to do so.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Evrenzo can have side effects.

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

Some possible side effects may be serious:

- Blood clots may form in your haemodialysis access (vascular access thrombosis or VAT) that cause the vascular access to close up or stop working if you are using a fistula or graft for dialysis access (may affect more than 1 in 10 people). Signs and symptoms may include swelling, redness, hardening or thickening of the skin around your access, oozing at the access site, or not feeling a vibration (“thrill”) over the access area. Contact your doctor straight away.
- Seizures, signs and symptoms may include headache, irritability, fear, confusion or unusual feelings; these may be warning signs a seizure (convulsions or fits) will occur (may affect up to 1 in 10 people). Contact your doctor straight away.
- Blood clots in the veins of your legs (deep vein thrombosis or DVT) (may affect up to 1 in 10 people). Signs and symptoms may include pain and/or swelling in the legs, cramping, a cool or pale leg, or a feeling of warmth in the affected leg. Contact your doctor straight away.

Other possible side effects

Common (may affect up to 1 in 10 people):

- Nausea

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

Reporting of side effects

You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8.

or

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By reporting side effects, you can help provide more information on the safety of Evrenzo.

5. How to store Evrenzo

Store all medicines out of reach of children.

Store below 30-°C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Leave the blisers in the carton until required for use.

6. Contents of the pack and other information

What Evrenzo contains

Evrenzo 20 mg:

The active substance is roxadustat. Each tablet contains 20 mg roxadustat.

Evrenzo 50 mg:

The active substance is roxadustat. Each tablet contains 50 mg roxadustat.

Evrenzo 70 mg:

The active substance is roxadustat. Each tablet contains 70 mg roxadustat.

Evrenzo 100 mg:

The active substance is roxadustat. Each tablet contains 100 mg roxadustat.

Evrenzo 150 mg:

The active substance is roxadustat. Each tablet contains 150 mg roxadustat.

The other ingredients are:

tablet core: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone, magnesium stearate.

film-coating: polyvinyl alcohol (E1203), talc (E553b), macrogol (E1521), Allura Red Aluminium Lake AC (E129), titanium dioxide (E171), lecithin (soya) (E322).

What Evrenzo looks like and contents of the pack

Evrenzo 20 mg are red, oval, film-coated tablets, debossed with “20” on one side.

Evrenzo 50 mg are red, oval, film-coated tablets, debossed with “50” on one side.

Evrenzo 70 mg are red, round, film-coated tablets, debossed with “70” on one side.

Evrenzo 100 mg are red, oval, film-coated tablets, debossed with “100” on one side.

Evrenzo 150 mg are red, almond-shaped, film-coated tablets, debossed with “150” on one side.

The tablets are provided in PVC/aluminium blisters in packs containing 12 film-coated tablets.

Holder of Certificate of Registration

Astellas Pharma (Pty) Ltd., 7 Mirage Road, Bedfordview, 2007, South Africa

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Evrenzo 20 mg: 55/8.5/0417

Evrenzo 50 mg: 55/8.5/0418

Evrenzo 70 mg: 55/8.5/0419

Evrenzo 100 mg: 55/8.5/0420

Evrenzo 150 mg: 55/8.5/0421

Access to the corresponding Professional Information

https://www.sahpra.org.za/pi-pil-repository/

or

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