Package leaflet: Information for the patient

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

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 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 is a medicine 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 adults with symptomatic anaemia that occurs in patients 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 might not receive enough oxygen. Anaemia can cause symptoms such as tiredness, weakness, or shortness of breath.

How Evrenzo works
Roxadustat works by increasing the level of HIF, a substance in the body which increases the production of red blood cells when oxygen levels are low. By raising HIF levels, the medicine increases the production of red blood cells and raises the levels of haemoglobin (the oxygen-carrying protein in red blood cells). This improves the oxygen supply to your body and may reduce your symptoms of anaemia.

2. What you need to know before you take Evrenzo

Do not take Evrenzo
- if you are allergic to peanut or soya.
- if you are allergic to roxadustat or any of the other ingredients of this medicine (listed in section 6).
- if you are more than 6 months pregnant (it is also better to avoid this medicine in the first 6 months, see Pregnancy section).
- if you are breast-feeding.

Warnings and precautions
Talk to your doctor or pharmacist before taking Evrenzo:

- if you have epilepsy or have ever had convulsions or fits.
- 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, feeling of burning when you pass urine, red or painful skin or sores on your body.
- if you have a liver disorder.

Chronic kidney disease and anaemia may increase the risk of cardiovascular events and death.

Managing your anaemia is important. Your doctor will monitor your haemoglobin and also consider your treatment regimen as anaemia treatment and switching between anaemia treatments may also have a negative impact on your cardiovascular health.

Talk to your doctor, or pharmacist straight away:

- if you get blood clots:
  1. in the veins of your legs (deep vein thrombosis or DVT), signs of which can include pain and/or swelling in the legs, cramping or a feeling of warmth in the affected leg;
  2. in the lungs (pulmonary embolism or PE), signs of which can include sudden shortness of breath, chest pain (usually worse with breathing), feeling of anxiety, dizziness, lightheadedness, or fainting; heart racing, coughing (sometimes with blood);
  3. in your haemodialysis access (vascular access thrombosis or VAT) that stop the vascular access from working; signs of this can 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;
- if you have a seizure (convulsion or fit) or possible warning signs that a seizure may occur, such as headache, irritability, fear, confusion or unusual feelings;
- if you have signs and symptoms of an infection, which include fever, sweating or chills, sore throat, runny nose, shortness of breath, feeling weak or faint, confusion, cough, vomiting, diarrhoea, or stomach pain, burning when you pass urine, red or painful skin or sores on your body;
- if you have signs and symptoms of a stroke (cerebrovascular accident), which include sudden weakness or numbness of the face, arm or leg, especially on one side of the body, sudden confusion, trouble speaking or understanding, sudden trouble seeing in one or both eyes, severe headache, loss of consciousness or fainting, seizures (fits), loss of coordination, loss of balance.

Misuse can lead to an increase in blood cells and consequently thicken the blood. This can cause life-threatening problems with the heart or blood vessels.

Children and adolescents
Do not give Evrenzo to children and adolescents aged under 18 years because there is not enough information about its use in this age group.

Other medicines and Evrenzo
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Evrenzo may affect the way these medicines work, or these medicines may affect how Evrenzo works.

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

- 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), such as sevelamer carbonate or calcium acetate. You must take Evrenzo at

least 1 hour after these medicines or supplements. Otherwise roxadustat will not be properly absorbed by your body.
- a medicine to treat gout called probenecid.
- medicines used to lower cholesterol, such as simvastatin, atorvastatin, or rosuvastatin (also called “statins”), or gemfibrozil.
- other medicines used to treat anaemia such as erythropoiesis-stimulating agents (ESAs).

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.

Pregnancy, breast-feeding and fertility
If you are pregnant, think you may be pregnant or are planning to have a baby, contact your doctor.

Evrenzo may harm your unborn baby. Evrenzo is not recommended in the first 6 months of pregnancy and must not be taken in the last 3 months of pregnancy. Women taking Evrenzo who are able to become pregnant should use an effective method of contraception during treatment with Evrenzo and for at least one week after the last dose of Evrenzo. 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. It is not known if Evrenzo passes into your breast milk and could harm your baby.

Driving and using machines
This medicine may affect your ability to drive or use machines. Seizures can occur as a side effect (see section 4).

Evrenzo contains lactose, soya lecithin and Allura Red AC aluminium lake
Evrenzo contains sugar (lactose), traces of peanut and soya (soya lecithin), and an azo colouring agent (Allura Red AC aluminium lake). If you have been told by your doctor that you have an intolerance to some sugars or are allergic to peanut, soya or azo colouring agents, contact your doctor before taking this medicine.

3. How to take Evrenzo

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

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

Your doctor will check your haemoglobin levels regularly and increase or lower your dose based on your haemoglobin levels.

Evrenzo is taken by mouth as tablets.

Taking Evrenzo

- Take your Evrenzo dose three times per week unless your doctor told you otherwise.
- Never take Evrenzo on consecutive days.
- Take Evrenzo on the same three days every week.
- Evrenzo can be taken with food or between meals.
- Swallow the tablets whole.
- Do not chew, break or crush the tablets.

Take Evrenzo at least 1 hour after you have taken 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).

Dosing Schedule
3 times a week dosing schedule
Evrenzo comes in a blister pack containing medicine for 4 weeks (12 tablets), divided into 4 rows. Each row contains 1 week of medicine (3 tablets). Make sure you take tablets from the same row for each week.

Your dose ranges from 20 mg three times per week up to a maximum 400 mg three times per week.

Different dosing frequencies
In exceptional cases (based upon your haemoglobin levels), your doctor may decide to lower your Evrenzo dose to 20 mg two times or one time per week. In this case your doctor will explain which days of the week you need to take your dose.

More than 1 tablet needed to make up a dose
In most cases you will have 1 blister package per month. If your dose requires more than 1 blister package, you will need to take a tablet from each blister per dosing day. Your doctor will explain when and how many tablets to take.

Your doctor will monitor your haemoglobin level and may temporarily stop your treatment if your haemoglobin level becomes too high. Do not restart your treatment until your doctor tells you to. Your doctor will tell you what dose of Evrenzo to take and when to start taking it again.

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.

If you forget to take Evrenzo

- Never take a double dose to make up for a forgotten dose.
- If more than 24 hours (1 day) remains before your next scheduled dose, take the missed dose as soon as possible and take the next dose on the next scheduled day.
- If less than 24 hours (1 day) remains before your next scheduled dose: skip the missed dose and take the next dose on the next scheduled day.

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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some possible side effects may be serious. Contact your doctor straight away if you get any of the following:

- blood clot in the veins of your legs (deep vein thrombosis or DVT) (common, may affect up to 1 in 10 people).
- blood clot in the lungs (pulmonary embolism) (uncommon, may affect up to 1 in 100 people).
- blood clot in your haemodialysis access (vascular access thrombosis or VAT) that causes the vascular access to close up or stop working if you are using a fistula or graft for dialysis access (very common, may affect more than 1 in 10 people).
- stroke (cerebrovascular accident) (uncommon, may affect up to 1 in 100 people).
- low levels of blood platelets (thrombocytopenia) (common, may affect up to 1 in 10 people) which may present as unexplained bruising or a rash of small patches of red appearing on the

skin (called petechiae), prolonged bleeding from skin cuts, bleeding from the gums or nose, blood in urine or stools, bleeding in the whites of your eyes.
- seizures and warning signs of seizures (convulsions or fits) (common, may affect up to 1 in 10 people).
- sepsis, a serious or in rare cases, life-threatening infection (common, may affect up to 1 in 10 people).
- redness and shedding of skin over a larger area of the body, which may be itchy or painful (exfoliative dermatitis) (frequency cannot be estimated from the available data).

Other possible side effects

Very common (may affect more than 1 in 10 people):

- increased amount of potassium
- high blood pressure (hypertension)
- feeling sick (nausea)
- diarrhoea
- swelling due to fluid retention in the extremities (peripheral oedema)

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

- difficulty in sleeping (insomnia)
- headache
- vomiting
- constipation
- low levels of blood platelets (thrombocytopenia)

Uncommon (may affect up to 1 in 100 people):

- increased amount of bilirubin in your blood

Not known (frequency cannot be estimated from the available data):

- thyroid function decreased
- blood copper increased

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Evrenzo

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 carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 other information

What Evrenzo contains

Evrenzo 20 mg:
- The active substance is roxadustat. Each film-coated tablet contains 20 mg roxadustat.

Evrenzo 50 mg:
- The active substance is roxadustat. Each film-coated tablet contains 50 mg roxadustat.

Evrenzo 70 mg:
- The active substance is roxadustat. Each film-coated tablet contains 70 mg roxadustat.

Evrenzo 100 mg:
- The active substance is roxadustat. Each film-coated tablet contains 100 mg roxadustat.

Evrenzo 150 mg:
- The active substance is roxadustat. Each film-coated tablet contains 150 mg roxadustat.

The other ingredients are:

- tablet core: lactose monohydrate, microcrystalline cellulose (E460), croscarmellose sodium (E468), povidone (E1201), magnesium stearate (E470b).
- film-coating: polyvinyl alcohol (E1203), talc (E553b), macrogol (E1521), Allura Red Aluminium Lake AC (E129), titanium dioxide (E171), lecithin (soya) (E322).

See section 2 “Evrenzo contains lactose, soya lecithin and Allura Red AC aluminium lake”.

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.

Each pack contains 12 x 1 film-coated tablets (tablets) in PVC/aluminium perforated unit dose blisters.

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