Approved Patient Information Leaflet for ZENOXPAR 600 mg

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ZENOXPAR 600 mg film-coated tablets

Linezolid

Sugar free.

Read all of this leaflet carefully before you are given ZENOXPAR

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

1. What ZENOXPAR is and what it is used for

ZENOXPAR contains the active substance linezolid.

Linezolid is an antibiotic and belongs to a group of medicines called oxazolidinone.

It works by stopping the growth of certain bacteria which cause infection and to treat bacterial infections against which linezolid is active.

2. What you need to know before you take ZENOXPAR

Do not take ZENOXPAR:

- if you are hypersensitive (allergic) to linezolid any of the other ingredients of **ZENOXPAR** (listed in section 6);
- if you are pregnant or breastfeeding;
- if you are taking or have taken, within the last 2 weeks another medicine known as a monoamine oxidase inhibitor (MAOI) (used to treat depression or Parkinson's disease);
- if you have uncontrolled high blood pressure, an overactive thyroid or you have been diagnosed with a tumour of the adrenal gland and are on medicines to treat these conditions;
- if you are taking medicines to treat anxiety, depression or other mental problems (e.g. citalopram, fluoxetine, amitriptyline, meperidine or buspirone).

Warnings and precautions

Take special care with **ZENOXPAR** and tell your doctor immediately:

- if you start to feel unusually tired or weak, you have fevers, chills, a cough or hoarseness, lower back pain or painful and difficult urination;
- if you are anaemic. Your doctor will perform regular blood tests to monitor your blood counts;
- if you start to develop severe diarrhoea;
- if you have recurrent nausea or vomiting, stomach pain, headache, body weakness or muscle cramps. You may have developed a side effect of this medicine called lactic acidosis;
- if you taking other medicines, especially treatment for depression;
- if you start to develop changes in your vision (e.g. loss of vision, blurring);

- if you experience any feeling of numbness in your hands and feet, or you have a burning sensation or pain;
- if you have a history of seizures (fits);
- if you are prone to infections;
- if you have kidney or liver problems;
- if you have high blood pressure;
- if you have the unusual syndrome of producing too much hormones;
- if you have a rare type of cancer which secretes certain chemicals into your bloodstream leading to hot, red flushing, diarrhoea, asthmatic-like wheezing, weight loss or gain, malnutrition, dehydration, weakness, muscle and joint aches and peptic ulcer;
- if you have a dangerous condition (rhabdomyolysis) where damaged skeletal muscle rapidly breaks down, releasing its contents into the bloodstream and potentially causing kidney damage. Symptoms include muscle pain, weakness and dark or cola-coloured urine, which can range from mild to severe;
- if you have too low levels of sodium in your blood (nausea (feeling sick), vomiting (being sick), shortness of breath, headache, dizziness, confusion, convulsions (fits), coma);
- if you have an overactive thyroid.

Children and adolescents

ZENOXPAR is not suitable for children under 12 years of age.

Other medicines and ZENOXPAR

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

- Monoamine oxidase inhibitors (MAOIs), you should not take ZENOXPAR if you are taking, or have recently taken another medicine called a monoamine oxidase inhibitor (MAOI).
- Please talk to your doctor or pharmacist if you are taking any of the following medicines:
    - Decongestants or flu remedies which contain medicines such as pseudoephedrine or phenylpropanolamine.
    - Medicines which may increase your blood pressure, such as dopamine or adrenaline.
    - Medicines for treating depression such as SSRIs (selective serotonin reuptake inhibitors).
    - An antibiotic used in tuberculosis such as rifampicin.
    - Medicines for thinning blood and prevent blood clots such as warfarin.

ZENOXPAR with food, drink and alcohol

ZENOXPAR may be taken with or without food.

Avoid eating and drinking foods with a high level of a substance called tyramine, e.g. mature cheese, yeast extracts, undistilled alcohol or fermented soya bean products like soya sauce.

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.

You should not take **ZENOXPAR** during pregnancy.

You should not take **ZENOXPAR** when breastfeeding. Discuss with your doctor when it is safe to restart breastfeeding after finishing your treatment.

Driving and using machines

ZENOXPAR may cause dizziness or changes to vision.

It is not always possible to predict to what extent **ZENOXPAR** may interfere with your daily activities. Please ensure that you do not engage in the above activities until you are aware of the measure to which **ZENOXPAR** affects you.

ZENOXPAR contains soya lecithin

ZENOXPAR may contain traces of soy protein. If you are allergic to soya do not use this medicine.

3. How to take ZENOXPAR

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

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

Swallow the tablet whole with a glass of water.

Your doctor will prescribe the correct dose for you.
Your doctor will tell you how long your treatment with **ZENOXPAR** will last. Treatment with **ZENOXPAR** usually lasts 2 to 4 weeks.

Adults and adolescents (12 years and older)
The usual dose is 600 mg orally every 12 hours depending on the type of infection.

If you have the impression that the effect of **ZENOXPAR** is too strong or too weak, tell your doctor or pharmacist.

If you take more ZENOXPAR than you should

In the event of overdosage consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre.

If you forget to take ZENOXPAR

If you miss a dose, take it as soon as you remember and then take the next dose at the correct interval thereafter (i.e. after 8 or 12 hours as directed). Do not take a double dose to make up for a forgotten dose. Do not take more than the daily amount of **ZENOXPAR** that has been prescribed for you in one day.

If you stop taking ZENOXPAR

DO NOT stop taking your tablets unless your doctor has instructed you to.

4. Possible side effects

ZENOXPAR can have side effects.

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

If any of the following happens, stop taking ZENOXPAR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **ZENOXPAR**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- severe diarrhoea or blood in the stool, abdominal or stomach cramps and pain and severe abdominal tenderness (pseudomembranous colitis),
- bleeding or bruising more easily than normal,
- fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration,
- frequent infections such as fever, severe chills, sore throat or mouth ulcers,
- too low levels of sodium in your blood (nausea (feeling sick), vomiting (being sick), shortness of breath, headache, dizziness, confusion, coma),
- convulsions (fits),
- if you keep experiencing nausea, vomiting and stomach pain,
- blurred vision or loss of vision,
- tingling or numbness in your fingers and toes dropping things from your hands regularly, feeling of weakness or heaviness in your arms and legs, sharp stabbing pains),
- agitation, confusion, delirium, rigidity, tremor, incoordination, seizure, rapid heartbeat, severe breathing problems and diarrhoea (suggestive of serotonin syndrome) while also taking antidepressants known as SSRIs,
- changes in the way your heart beats, for example, if you notice it beating faster,
- pancreatitis (nausea, vomiting, fever, pain in your stomach area radiating to your back),
- gastritis (pain, nausea, vomiting, vomiting blood, blood in the stool),
- yellowing of skin and eyes, dark urine and tiredness which may e symptoms of liver problems,
- painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis,
- a dangerous condition (rhabdomyolysis) where damaged skeletal muscle rapidly breaks down, releasing its contents into the bloodstream and potentially causing kidney damage. Symptoms

include muscle pain, weakness and dark or cola-coloured urine, which can range from mild to severe
- producing an abnormally large amount of urine.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache,
- fungal infection in the mouth or in vagina,
- difficulty sleeping,
- metallic taste and dizziness,
- high blood pressure,
- constipation and indigestion.

Less frequent side effects:

- inflammation of the vagina,
- ringing in the ears,
- tenderness and redness under the skin,
- dry mouth, inflamed mouth and lips,
- discoloration of tongue and teeth,
- swollen red bumps on the skin (hives),
- chills, tiredness, feeling thirsty,
- high sugar (glucose) levels in the blood (passing large amounts or urine, excessive thirst, dry mouth and skin),
- low blood pressure,

- excessive, sudden or unexplained sweating,
- itching, burning, irritation and unusual vaginal discharge.

Frequency unknown side effects:

- hair loss (temporary).

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

5. How to store ZENOXPAR

Store all medicines out of reach of children.

Store at or below 25 °C.

6. Contents of the pack and other information

What ZENOXPAR contains

The active substance is linezolid.

Each film-coated tablet contains 600 mg linezolid.

The other ingredients are:

- *Magnesium stearate, microcrystalline cellulose, hydroxypropyl cellulose (hyprolose) & sodium starch glycolate (Type A).*

- *Film coating (Opadry white): polyvinyl alcohol (E1203), titanium dioxide (E171), talc (E553b), soya lecithin (E322) & xanthan gum (E415).*

What ZENOXPAR looks like and contents of the pack

ZENOXPAR 600 mg: White to off-white, oval shaped, biconvex film-coated tablets, debossed with "EQ1" on one side and plain on the other side.

ZENOXPAR 600 mg film-coated tablets are packed in:

- Alu-Alu blister packs comprising lidding foil made of hard tampered aluminium foil with HSL coating on bright side and cold formable, triple laminated aluminium foil as forming foil. Blisters are packed in a carton along with package leaflet.
- Wide mouth white opaque HDPE container fitted with white opaque polypropylene child resistant closure or continuous thread screw closure (with wad having induction sealing liner) and a desiccant disc.

Pack sizes:

Each box of Alu-Alu blister contains 10, 20, 30, 50, 60 or 100 tablets.

Each HDPE bottle contains 30, 100 or 500 tablets.

Not all pack sizes will be marketed.

Holder of Certificate of Registration

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