

## Package leaflet: Information for the user

### Linezolid Polpharma 600 mg, filmomhulde tabletten

#### Linezolid

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

#### **1. What Linezolid Polpharma tablets is and what it is used for**

Linezolid Polpharma tablets is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria (germs) that cause infections. It is used to treat pneumonia and some infections in the skin or under the skin in adults. Your doctor will have decided if this medicine is suitable to treat your infection.

#### **2. What you need to know before you take Linezolid Polpharma tablets**

##### **Do not take Linezolid Polpharma tablets:**

- if you are allergic to linezolid or any of the other ingredients of this medicine (listed in section 6).
- if you are taking or have taken within the last 2 weeks any medicines known as monoamine oxidase inhibitors (MAOIs for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat depression in Parkinson's disease
- if you are breastfeeding. This is because linezolid passes into breast milk and could affect the baby.

##### **Warnings and precautions**

Linezolid Polpharma tablets may not be suitable for you if you answer **yes** to any of the following questions. In this case tell your doctor as he/she will need to check your general health and your blood pressure before and during your treatment or may decide that another treatment is better for you.

Ask your doctor if you are not sure whether these categories apply to you.

- Do you have high blood pressure?
- Have you been diagnosed with an overactive thyroid?
- Do you have a tumour of the adrenal glands (phaeochromocytoma) or carcinoid syndrome (caused by tumours of the hormone system with symptoms of diarrhoea, flushing of the skin, wheezing)?
- Do you suffer from manic depression, schizoaffective disorder, mental confusion or other mental problems?
- Do you take any opioids?
- Are you taking any of the following medicines?
  - decongestant, cold or flu remedies containing pseudoephedrine or phenylpropanolamine

- medicines used to treat asthma such as salbutamol, terbutaline, fenoterol
- antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors) for example amitriptyline, ciproamil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine; sertraline
- medicines used to treat migraine such as sumatriptan and zolmitriptan
- medicines used to treat sudden, severe allergic reactions such as adrenaline (epinephrine)
- medicines which increase your blood pressure, such as noradrenaline (norepinephrine), dopamine and dobutamine
- opioids e.g., pethidine - used to treat moderate to severe pain
- medicines used to treat anxiety disorders, such as buspirone
- an antibiotic called rifampicin

Tell your doctor before you are treated with this medicine if you:

- bruise and bleed easily
- are anaemic (have low red blood cells)
- are prone to getting infections
- have a history of seizures
- have liver problems or kidney problems particularly if you have dialysis
- have diarrhoea

Tell your doctor immediately if during treatment you suffer from:

- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- loss of sensitivity in your arms or legs or a sensation of tingling or pricking in your arms or legs.
- you may develop diarrhoea while taking or after taking antibiotics, including Linezolid Polpharma tablets. If this becomes severe or persistent or you notice that your stool contains blood or mucus, you should stop Linezolid Polpharma tablets treatment immediately and consult your doctor. In this situation, you should not take medicines that stop or slow bowel movement.
- recurrent nausea or vomiting, abdominal pain or rapid breathing

The use of certain medicines, including antidepressants and opioids, together with Linezolid Polpharma can lead to serotonin syndrome, a potentially life-threatening condition (see section 2 “Other medicines and Linezolid Polpharma” and section 4).

### **Other medicines and Linezolid Polpharma tablets**

There is a risk that Linezolid Polpharma tablets may sometimes interact with certain other medicines to cause side effects such as changes in blood pressure, temperature or heart rate.

**Tell your doctor if you are taking or have taken within the last 2 weeks** the following medicines as Linezolid Polpharma tablets **must not** be taken if you are already taking these medicines or have taken them recently. (See also Section 2 above ‘Do not take Linezolid Polpharma tablets’)

- monoamine oxidase inhibitors (MAOIs for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat depression or Parkinson’s disease

Also tell your doctor if you are taking the following medicines. Your doctor may still decide to give you Linezolid Polpharma tablets, but will need to check your general health and your blood pressure before and during your treatment. In other cases, your doctor may decide that another treatment is better for you.

- Decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine.
- Some medicines used to treat asthma such as salbutamol, terbutaline, fenoterol.
- Certain antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors). There are many of these, including amitriptyline, ciproamil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, sertraline.

- Medicines used to treat migraine such as sumatriptan and zolmitriptan.
- Medicines used to treat sudden, severe allergic reactions such as adrenaline (epinephrine).
- Medicines which increase your blood pressure, such as noradrenaline (norepinephrine), dopamine and dobutamine
- Opioids e.g., pethidine - used to treat moderate to severe pain.
- Medicines used to treat anxiety disorders, such as buspirone.
- Medicines that stop blood clotting, such as warfarin.

Tell your doctor if you are taking, have recently taken or might take any other medicines.

### **Linezolid Polpharma tablets with food, drink and alcohol**

- Avoid eating large amounts of mature cheese, yeast extracts, or soya bean extracts e.g. soy sauce and drinking alcohol, especially draught beers and wine. This is because this medicine may react with a substance called tyramine, which is naturally present in some foods. This interaction may cause an increase in your blood pressure.
- If you develop a throbbing headache after eating or drinking, tell your doctor or pharmacist immediately.

### **Pregnancy, breast-feeding and fertility**

The effect of Linezolid Polpharma tablets in pregnant women is not known. Therefore you should not take this medicine if you are pregnant, unless your doctor advises it. If you are pregnant think you may be pregnant or are planning to have a baby ask your doctor for advice before taking this medicine.

You must not breastfeed when taking Linezolid Polpharma tablets because it passes into breast milk and could affect the baby.

### **Driving and using machines**

Linezolid Polpharma tablets may make you feel dizzy or experience problems with your vision. If this happens, do not drive or operate any machinery. Remember that if you are unwell your ability to drive or operate machinery may be affected.

### **Medicine contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take Linezolid Polpharma tablets**

### **Adults**

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

The usual dose is one tablet (600 mg) twice daily (every twelve hours). Swallow the tablet whole with some water.

You can take your tablet before, during or after a meal.

If you are on kidney dialysis, you should take this medicine after dialysis.

A course of treatment usually lasts 10 to 14 days, but can last up to 28 days. The safety and effectiveness of this medicine have not been established for treatment periods longer than 28 days. Your doctor will decide how long you should be treated.

While you are taking Linezolid Polpharma tablets, your doctor should perform regular blood tests to monitor your blood count.

Your doctor should monitor your eyesight if you take this medicine for more than 28 days.

#### **Use in children and adolescents**

Linezolid Polpharma tablets is not recommended in children and adolescents (under 18 years old).

#### **If you take more Linezolid Polpharma tablets than you should**

Tell your doctor or pharmacist at once.

#### **If you forget to take Linezolid Polpharma tablets**

Take the forgotten tablet as soon as you remember. Take the next tablet 12 hours after this and continue taking your tablets every 12 hours. Do not take a double dose to make up for the forgotten tablet.

#### **If you stop taking Linezolid Polpharma tablets**

Unless your doctor instructs you to stop treatment, it is important to continue taking Linezolid Polpharma tablets.

If you stop and your original symptoms come back tell your doctor or pharmacist immediately.

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.

**Tell your doctor or pharmacist immediately** if you notice any of these side effects during your treatment with Linezolid Polpharma tablets:

- skin reactions such as red sore skin and flaking (dermatitis), rash, itching, or swelling, particularly around the face and neck. This may be the sign of an allergic reaction and it may be necessary for you to stop taking Linezolid Polpharma tablets.
- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which in very rare circumstances may develop into complications that are life-threatening.
- recurrent nausea or vomiting, abdominal pain or rapid breathing.
- fits or seizures have been reported with this medicine.
- serotonin syndrome (frequency not known): you should let your doctor know if you experience 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 or opioids (see section 2).

Numbness, tingling or blurred vision have been reported by patients who have been given this medicine for more than 28 days. If you experience difficulties with your vision you should consult your doctor as soon as possible.

#### **Other side effects include:**

#### **Common side effects: (may affect up to 1 in 10 people):**

- Fungal infections especially vaginal or oral “thrush”
- Headache

- Metallic taste in the mouth
- Diarrhoea, nausea or vomiting
- Changes in some blood test results including those measuring your kidney or liver function or blood sugar levels
- Unexplained bleeding or bruising, which may be due to changes in the numbers of certain cells in the blood which may affect blood clotting or lead to anaemia
- Difficulty in sleeping
- Increased blood pressure
- Anaemia (low red blood cell count)
- Changes in numbers of certain cells in the blood which may affect your ability to fight infection
- Skin rash
- Itching skin
- Dizziness
- Localised or general abdominal pain
- Constipation
- Indigestion
- Localised pain
- Fever

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

- Inflammation of the vagina or genital area in women
- Sensations such as tingling or feeling numb
- Blurred vision
- “Ringing” in the ears (tinnitus)
- Inflammation of the veins
- Dry or sore mouth, swollen, sore, or discoloured tongue
- A need to urinate more often
- Chills
- Feeling tired or thirsty
- Inflammation of the pancreas
- Increased sweating
- Changes in proteins, salts or enzymes in the blood which measure kidney or liver function.
- Convulsions
- Hyponatraemia (low blood sodium levels)
- Kidney failure
- Reduction in platelets
- Abdominal bloating
- Transient ischaemic attacks (temporary disturbance of blood flow to the brain causing short term symptoms such as loss of vision, leg and arm weakness, slurring of speech and loss of consciousness)
- Inflammation of the skin
- Increase in creatinine
- Stomach pain
- Changes in heart rate (e.g. increase rate)

**Rare side effects: (may affect up to 1 in 1000 people):**

- Restricted field of vision
- Superficial tooth discolouration, removable with professional dental cleaning (manual descaling)

**The following side effects have also been reported (frequency not known):**

- Serotonin syndrome (symptoms include fast heart rate, confusion, abnormal sweating, hallucinations, involuntary movements chills and shivering),
- Lactic acidosis (symptoms include recurrent nausea and vomiting, abdominal pain rapid breathing)
- Severe skin disorders

- Sideroblastic anaemia (a type of anaemia (low red blood cell count))
- Alopecia (hair loss)
- Changes in colour vision or difficulty in seeing detail
- Decrease of the blood cell count
- Weakness and/or sensory changes

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Linezolid Polpharma tablets

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.

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

- The active substance is linezolid. Each tablet contains 600 mg of linezolid.
- The other ingredients are: Sodium starch glycolate, Microcrystalline cellulose PH 101, Microcrystalline cellulose PH 102, Povidone, Sodium dihydrogen citrate powder type F0100, Magnesium stearate and Film coating that contains: Hypromellose, Microcrystalline cellulose, Macrogol stearate 40 and Titanium dioxide (E171)

### What Linezolid Polpharma tablets looks like and contents of the pack

Linezolid Polpharma 600 mg tablets are off-white, oblong, biconvex film-coated tablets

The tablets are available as blister strips of 10 tablets packed in a box. Each box contains 10, 20, 30, 50 or 60 tablets. The tablets are also available in a box containing 100 tablets for hospital use only.

Not all pack sizes may be marketed

### Marketing Authorisation Holder

Pharmaceutical Works POLPHARMA S.A.  
19, Pelplińska Street  
83-200 Starogard Gdański

### Manufacturer

Pharmaceutical Works POLPHARMA S.A.  
19, Pelplińska Street  
83-200 Starogard Gdański

### Marketing Authorisation Number

RVG 114804

**This medicinal product is authorised in the Member States of the EEA under the following names:**

<{Name of the Member State}> <{Name of the medicinal product}>

**This leaflet was last revised in February 2024.**

**Other sources of information**

Detailed information on this medicine is available on the web site of {MA/Agency}