

## PATIENT INFORMATION LEAFLET

### **POLĪNOKSĪD 2 mg/ml Solution for I.V. Infusion**

**For intravenous administration.**

**Sterile**

- **Active substance:** Each 1 ml solution for infusion contains 2 mg of linezolid.
- **Excipients:** Sodium citrate dihydrate, citric acid anhydrous, dextrose (glucose) anhydrous, water for injection.

**Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.**

- *Keep this PATIENT INFORMATION 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. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow the written instructions exactly. Do not use **higher or lower** dose than the recommended dose.*

#### **The following subjects are covered herein:**

**1. What POLĪNOKSĪD is and what it is used for?**

**2. Before you are given POLĪNOKSĪD**

**3. How you will POLĪNOKSĪD ?**

**4. Possible side effects**

**5. How to store POLĪNOKSĪD ?**

**1. What POLĪNOKSĪD is and what it is used for?**

- POLĪNOKSĪD is an antibiotic of the oxazolidinones group that works by stopping the growth of certain types of bacteria. It is used to treat pneumonia and some infections in the skin or under the skin.
- POLĪNOKSĪD is a liquid that is slowly given to the vein with the aid of a plastic tube. This is called an intravenous infusion or “a drip into the vein”. Linezolid, the active substance of POLĪNOKSĪD belongs to an antibacterial drug group.

- Disposable, ready-to-use infusion bags contain 300 ml (600 mg linezolid active) solution and are packed in boxes. It is presented as 1 infusion bag.
- POLĪNOKSĪD is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria. It is used to treat pneumonia and some infections in the skin or under the skin.

## **2. Before you are given POLĪNOKSĪD**

### **DO NOT USE POLĪNOKSĪD under the following circumstances:**

- If you are allergic (hypersensitivity) to linezolid or any of the other excipient listed above.
- If you are taking or have taken within the last 2 weeks any medicines known as monoamine oxidase inhibitors (for example phenelzine, isocarboxazid, selegiline, moclobemide). These medications may be used to treat depression or Parkinson's disease;
- If you are breast-feeding. This is because linezolid passes into breast milk and could affect the baby.
- POLĪNOKSĪD may not be suitable for you if you have any of the following.
- Your doctor may request a detailed control to check your general health and your blood pressure. In some cases he/she may decide that another treatment is better for you.
- Ask your doctor if you are not sure whether these categories apply to you.
- If you have high blood pressure and whether or not you are taking medicines for this,
- If you have you been diagnosed with an overactive thyroid,
- If you have a tumour of the adrenal glands (phaeochromocytoma) or symptoms of diarrhoea, flushing of the skin, wheezing caused by tumours of the hormone system (carcinoid syndrome),
- If you suffer from manic depression, schizoaffective disorder, mental confusion or other mental problems
- If you are taking any of the following medicines:
- Drugs that relieve nasal congestion (decongestant) or cold and flu remedies containing pseudoephedrine or phenylpropanolamine.
- Some medicines used to treat asthma such as salbutamol, terbutaline, fenoterol.
- Antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors), including amitriptyline, sipramil, clomipramine, doxepin, 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 blood pressure, such as noradrenaline (norepinephrine), dopamine and dobutamine

- Medicines used to treat moderate to severe pain, such as pethidine.
- Medicines used to treat anxiety disorders, such as buspirone.
- An antibiotic called rifampicin.

### **USE POLINOKSID with CAUTION if**

Tell your doctor before you take POLINOKSID 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 are on dialysis
- have diarrhoea
- have diabetes

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.
- diarrhoea while taking or after taking antibiotics, including POLINOKSID . If this becomes severe or persistent or you notice that your stool contains blood or mucus, you should stop taking POLINOKSID immediately and consult your doctor. In this situation, you should not take medicines that stop or slow bowel movement.  
This can be the inflammation of the intestine that can occur following treatment with antibiotics.
- recurrent nausea or vomiting, abdominal pain or rapid breathing

“Please consult your doctor even if these warnings apply to you at any time in the past.”

### **Using POLINOKSID with food and beverages**

- You can take POLINOKSID either before, during or after a meal.
- 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 while taking POLINOKSID . This is because this medicine may react with a substance called tyramine which is naturally present in some foods and may cause an increase in your blood pressure.
- If you develop a throbbing headache after eating or drinking, tell your doctor, pharmacist or nurse immediately.

### **Pregnancy**

*Before using this medicine consult your doctor or pharmacist.*

The effect of POLINOKSID in pregnant women is not known. Therefore it should not be used in pregnancy unless advised by your doctor. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

*If you notice that you have been pregnant during treatment, stop using the drug immediately, consult your doctor or pharmacist.*

### **Breastfeeding**

*Before using this medicine consult your doctor or pharmacist.*

You should not breast-feed when using POLINOKSID because it passes into breast milk and could affect the baby.

### **Ability to drive and use machines**

POLINOKSID may make you feel dizzy or experience problems with your vision. If you feel that way, remember that your ability to drive or operate machinery may be affected.

### **Important information regarding some of the excipients contained in POLINOKSID**

This medicine contains glucose and sodium citrate with other excipients.

This product contains 45,67 mg of glucose. This should be taken into account in patients with diabetes mellitus.

Each 1000 ml of solution also contains 16,7 mmol of sodium. The sodium content should be taken into account in patients on a controlled sodium diet.

### **Use in combination with other drugs**

There is a risk that POLINOKSID 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.**

Do not take POLINOKSID if you are already taking these medicines or have taken them recently.

- Monoamine oxidase inhibitors (for example phenelzine, isocarboxazid, selegiline, moclobemide) 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 POLINOKSID, but will need to check your general health and your blood pressure before and during your treatment. In some cases he/she may decide that, another treatment is better for you.
- Drugs that relieve nasal congestion (decongestant) or cold and flu remedies containing pseudoephedrine or phenylpropanolamine.

- Some medicines used to treat asthma such as salbutamol, terbutaline, fenoterol.
- Antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors), including amitriptyline, sipramil, clomipramine, doxepin, 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 blood pressure, such as noradrenaline (norepinephrine), dopamine and dobutamine
- Medicines used to treat moderate to severe pain, such as pethidine.
- Medicines used to treat anxiety disorders, such as buspirone.
- Medicines that stop blood clotting, such as warfarin..

*If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.*

### **3. How you will be given POLINOKSID ?**

#### **Instructions regarding correct use and dosage/administration frequency:**

“Your doctor will determine the dosage of your drug depending on your illness and will apply it to you”

This medicine will be given to you through a drip (by infusion into a vein) by a doctor or healthcare professional. The recommended dose for adults (18 years and older) is 300 ml (600 mg linezolid) twice daily which is given directly into the blood stream (intravenously) by a drip over a period of 30 to 120 minutes.

A course of treatment usually lasts 10 to 14 days, but can last up to 28 days.

The safety and effectiveness of POLINOKSID have not been established for treatment periods longer than 28 days. Your doctor will decide how long you should be treated.

While you are using POLINOKSID , your doctor should perform regular blood tests to monitor your blood count.

Your doctor should monitor your eyesight if you use POLINOKSID for more than 28 days.

#### **Route and method of administration:**

Through a drip into the vein.

#### **Different age groups:**

##### **Use in children:**

In children, the dose of POLINOKSID is determined by your doctor according to age and body weight.

**Use in elderly:**

Your doctor will not make a special dose adjustment for you.

**Special usage cases:****Renal failure:**

Your doctor will not make a special dose adjustment for you.

If you are on kidney dialysis, you should be given the medicine after your dialysis treatment.

**Liver failure:**

Your doctor will not make a special dose adjustment for you.

*If you have the impression that the effect of POLINOKSID is too strong or weak, talk with your doctor or pharmacist.*

**If you have taken more POLINOKSID than you should have:**

*If you used more POLINOKSID than was prescribed, tell your doctor or pharmacist.*

**If you forget to take POLINOKSID :**

*Do not take double dose to make up the dose you have missed.*

As you will be given this medicine under close supervision, it is very unlikely that you will miss a dose. If you think that you have missed a dose of treatment, tell a doctor or nurse at once.

**Possible effects once POLINOKSID treatment is concluded:**

As long as your doctor tells you not to stop your treatment, continue to use POLINOKSID .

When your treatment with POLINOKSID ends, you should talk to your doctor or pharmacist immediately if the actual symptoms occur again.

**4. Possible side effects**

Like all medicines, POLINOKSID may cause side effects in patients sensitive to its ingredients.

**If you notice any of the following side effects stop using POLINOKSID and tell your doctor IMMEDIATELY or apply to the emergency department of the nearest hospital:**

The following side effects are serious side effects:

- Serious skin conditions (unknown), skin reactions such as swelling in the face and neck (unknown), wheezing and / or difficult breathing (unknown). This may be the sign of an allergic reaction and it may be necessary for you to stop taking POLINOKSID .

- Very red skin and flaking (dermatitis) (uncommon), rash (common), itching (common)
- Problems with your vision such as blurred vision (uncommon), change in colors (unknown) hemianopsia, difficulty in seeing detail if your field of vision becomes restricted (unknown).
- Severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis) In rare circumstances this may develop into complications that are life-threatening. This can be the inflammation of the intestine that can occur following treatment with antibiotics.
- Recurrent nausea or vomiting, abdominal pain or rapid breathing (unknown)
- Fits or seizures (uncommon). You should let your doctor know if you experience agitation, confusion, sudden transient loss of consciousness (delirium) showing symptoms such as expansiveness, delusion, muscle rigidity, tremor, coordination impairment and seizure (unknown) while also taking antidepressants known as SSRIs.
- Bleeding or bruising (common), which may occur due to changes in the number of certain cells in the blood that can affect blood clotting or cause anemia.
- Change in the number of certain cells in the blood that affect your fight against infection. It can cause signs of infection, such as fever (common), sore throat (uncommon), mouth sores (uncommon), and fatigue (uncommon).
- Pancreatic inflammation (uncommon)
- Remittance (convulsion) (uncommon)
- Temporary ischemic crises (Due to temporary deterioration of blood flow to the brain, it causes short-term symptoms such as vision loss, leg and arm weakness, speech impairment and loss of consciousness.) (Uncommon)
- Tinnitus (uncommon)

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

These are all very serious side effects. If you have one of these, you may need an emergency medical intervention or hospitalization.

**Other side effects:**

Side effects are listed as defined by following categories:

Very common: may be seen in at least one of 10 patients;

Common: may be seen in less than one of 10 patients but more than one of 100 patients;

Uncommon: may be seen in less than one of 100 patients but more than one of 1,000 patients;

Rare: may be seen in less than one of 1,000 patients but more than one of 10,000 patients;

Very rare: may be seen in at least one of 10,000 patients;

Unknown: Cannot be estimated from the available data.

**Common:**

- 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
- Hemorrhage or bruising, which affects blood clotting or cause anemia, due to a change in the number of specific cells of unknown cause
- Difficulty in sleeping
- Increased blood pressure
- Anaemia (low red blood cell)
- Change in the number of specific blood cells that affect your ability to fight infection
- Skin rash
- Itching on the skin
- Dizziness
- Localised or general abdominal pain
- Constipation
- Indigestion
- Localised pain
- Fever

**Uncommon:**

- Inflammation of the vagina or genital area in women
- Reduced number of certain blood cells that affect your ability to fight infection
- In women, vulvovaginal disorders of the reproductive organs
- Sensitivity such as tingling or feeling numb
- Blurred vision
- Tinnitus
- Inflammation of the veins
- Dry mouth or mouth ulcers, swollen, sore, or discoloured tongue
- A need to urinate more often
- Chills
- Fatigue or feeling thirsty
- Inflammation of the pancreas
- Increased sweating
- Changes in proteins, salts or enzymes in the blood which measure kidney or liver function
- Hives
- Gastritis
- Tongue inflammation
- Loose stool
- Inflammation in the mouth

- Convulsion
- Blood sodium level below normal (hyponatremia)
- Renal failure
- Decrease in the number of blood cells (platelets) that help blood coagulate
- Abdominal swelling
- 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)
- Pain at the injection site
- Inflammation of the skin
- Increase in creatinine level
- Stomach pain
- Changes in heart rhythm (such as increased rhythm)
- Reduced blood sugar

**Rare:**

- Limited visual field, hemianopsia
- Superficial tooth discolouration, removable with professional dental cleaning
- Enteritis with bloody, watery diarrhea due to prolonged use of antibiotics
- Reduction of defensive cells and blood platelets with anemia (pancytopenia)

**The following side effects have also been reported (frequency unknown):**

- Serotonin syndrome symptoms (rapid heartbeat, confusion, excessive sweating, imaginary sweating and tremors)
- Signs of lactic acidosis (recurrent vomiting and nausea, abdominal pain, rapid breathing)
- Severe skin disorders, such as Stevens-Johnson Syndrome (inflammation with infiltration of blood, swelling and redness on the skin and around the eyes) and toxic epidermal necrolysis (a serious disease with blisters on the skin)
- Sideroblastic anemia (a type of anemia (having a low number of red blood cells))
- Bone marrow suppression (myelosuppression)
- Very severe response to allergy-causing substances of the body, sudden hypersensitivity (anaphylaxis)
- Reduced blood sugar (Hypoglycemia)
- Hair loss (alopecia)
- Difficulty seeing color changes or details
- Decrease in blood cell count
- Weakness and / or sensory changes
- Swelling of the face and throat due to allergy (angioedema)
- Damage to nerves attached to the brain and spinal cord from other parts of the body (peripheral neuropathy)

- Damage to visual nerves (optic neuropathy), inflammation of visual nerves (optic neuritis), loss of sight

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

## **5. How to store POLİNOKSİD ?**

*Keep POLİNOKSİD out of the sight and reach of children, and in its original packaging.*

### **Use in compliance with the expiry date.**

Store the bags in the foil packaging until ready to use.

The bags should be used immediately after opening. Any unused solution must be discarded. Store at room temperature below 25°C. Do not freeze. POLİNOKSİD Solution for infusion may turn into yellow over time, but the potency is not adversely affected.

Do not dispose of expired or unused drugs! Give to the collection system determined by the Ministry of Environment and Urbanization.

*Do not use POLİNOKSİD after the expiry date which is stated on the packaging.*

POLİNOKSİD solution for IV infusion is known to be compatible with following solutions:

- 5% Dextrose injection
- 0.9% sodium chloride injection
- Ringer lactate injection

### ***Marketing Authorisation Holder and Manufacturing Site:***

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*This patient leaflet was approved on 04/05/2020*