PACKAGE LEAFLET

LINEDOR 600 mg/300 ml I.V. solution for infusion, Vial

Administered into vein.

- ***Active Substance*:** Each vial contains 600 mg linezolid as active substance**.**
- ***Excipient(s):*** Sodium citrate, citric acid anhydrous, glucose monohydrate, sodium chloride, sodium hydroxide, water for injection.

Please read this entire leaflet carefully before you start having 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. Do not pass it on to others.*
- *While you are using this medicine, if you go to a doctor or a hospital, tell your doctor that you are using this medicine.*
- *Follow the instructions, written in this leaflet, exactly. Do not use **higher or lower doses** other than the recommended dose to you.*

This leaflet includes following topics:

1. What LINEDOR is and what it is used for?

- LINEDOR is a liquid that is slowly given through the vessel with a plastic tube. This application is called intravenous infusion or ‘’drop by drop into the vessel’’. The active substance linezolid of LINEDOR is included in an antibacterial drug group.
- LINEDOR is presented to usage in cardboard box with vial that contains solution for infusion, covered by bromobutyl stopper, white flip-off closure.
- LINEDOR is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria. It is used to treat pneumonia or some infections in the skin or under the skin.

2. Before you use LINEDOR

Do not use LINEDOR

- If you are allergic to the active substance content linezolid or any of the excipient listed above (hypersensitivity).
- If you are taking one of the drugs from the monoamine oxidase inhibitor group (e.g. phenelzine, isocarboxazid, selegiline, moclobemide) or if you have used it up to two weeks before. These can be used for treatment of depression or Parkinson disease.

If any of the following situations exist, LINEDOR may not be appropriate for you.
Your doctor may ask detailed control to evaluate your general situation and blood pressure. In some cases, your doctor may decide that another treatment is better for you.

If you are not sure whether these categories apply to you, ask your doctor.

- If you have high blood pressure, if you are using or not using medicine for this condition,
- If an overactive thyroid is diagnosed,
- If there are symptoms such as diarrhea, skin redness, wheezing of breath (carcinoid syndrome) due to tumor in the adrenal gland (pheochromocytoma) or tumor in the hormone system,
- If you have manic depression, schizoaffective disorder, mental confusion or other mental problems,
- If you are using any of the below drugs:
    - Cold and flu drugs containing pseudoephedrine or phenylpropanolamine or drugs eliminating nasal obstruction (decongestant)
    - Some medicines used to treat asthma such as salbutamol, terbutaline, fenoterol
    - Depression medicines such as amitriptyline, cipramil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, sertraline, known as tricyclic or SSRI (selective serotonin reuptake inhibitors)
    - 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 noradrenalin(norepinephrine), dopamine and dobutamine
    - Medicines used to decrease severe pain, such as pethidine
    - Medicines used in anxiety disorders, such as buspirone.

Take special care with LINEDOR

Talk to your doctor before taking LINEDOR if you,

- bruise and bleed easily
- are anemic
- are prone to getting infections
- have a history of seizures
- have liver problems or kidney problems particularly while you are having dialysis
- have diarrhea

Tell your doctor immediately if during treatment you suffer from:

- Problems with your vision such as blurred vision, changes in color vision, difficulty in seeing detail, field of vision disorder.
- If you have diarrhea especially bloody diarrhea, your treatment may need to be discontinued. This may be the inflammation of the intestine that can occur following treatment with antibiotics.
- Recurrent nausea or vomiting, abdominal pain or over breathing.

Please consult your doctor if any of these warnings apply to you even if any time in past.

Use of LINEDOR with food and beverage

- LINEDOR can be taken 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. This is because this medicine may react with a substance called tyramine which is naturally present in some foods and cause an increase in your blood pressure.
- If you develop a throbbing headache after eating or drinking, tell your doctor or pharmacist immediately.

Pregnancy

Before using the drug consult your doctor or pharmacist.

The effect of LINEDOR in pregnant women is not known. Therefore it should not be taken in pregnancy unless advised by your doctor. Tell your doctor if you are pregnant, or desire to be pregnant.

If you notice that you are pregnant during the treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Before using the drug consult your doctor or pharmacist.

It is not known whether LINEDOR passes through the breast milk. While deciding whether you will stop or not stop the lactation, or whether you will terminate or not terminate LINEDOR treatment/ avoid or not avoid the treatment, your doctor will take into consideration benefit of breastfeeding to your baby and benefit of LINEDOR treatment in terms of nursing mother.

Driving and using machines

LINEDOR may make you feel dizzy. If you feel this way, do not use it because LINEDOR may affect your driving and using machine ability.

Important information on some ingredients of LINEDOR

This medicinal product contains 15 g glucose per vial. This should be considered in patients with diabetes mellitus.

This medicinal product contains 1262 mg sodium per vial. This should be considered for patients on a controlled sodium diet.

Taking other medicines

Sometimes LINEDOR interacts with certain medicines, there is a risk that LINEDOR may cause side effects such as changes in blood pressure, body temperature, or heart rate.

Tell your doctor if you are taking one of the following medicines or if you have used it two weeks in advance.

If you are currently using these medications or have used them in the near future, do not take LINEDOR.

- Drugs belonging to the group of monoamine oxidase inhibitors used in the treatment of depression or Parkinson disease (e.g. phenelzine, isocarboxazid, selegiline, moclobemide).

Also tell your doctor if you are taking the following medicines. Your doctor may still decide to give you LINEDOR, 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.

- Cold and flu drugs containing pseudoephedrine or phenylpropanolamine or decongestant drugs.

- Some medicines used to treat asthma such as salbutamol, terbutaline, fenoterol
- Depression medicines such as amitriptyline, cipramil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, sertraline, known as tricyclic or SSRI (selective serotonin reuptake inhibitors).
- 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 noradrenalin (norepinephrine), dopamine and dobutamine.
- Medicines used to decrease severe pain, such as pethidine
- Medicines used in anxiety disorders, such as buspirone.
- Medicines that stop blood clotting, such as warfarin.

If you are using or have recently used any prescribed or unprescribed medicine, please give information to your doctor or pharmacist.

3. How to use LINEDOR

Instructions for appropriate usage and dose / frequency of application:

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 by a doctor or health personnel drop by drop (by intravenous infusion). For adults (18 years and over), the dose will be administered to you by directly given to blood (into vein) of 300 ml (600 mg linezolid) twice a day for 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 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 LINEDOR, your doctor will perform regular blood tests to monitor your blood count. Your doctor will monitor your eyesight if you take LINEDOR for more than 28 days.

Administration route and method:

It is administered drop by drop into vein.

Different Age Groups:

Usage in Children:

Your doctor will determine LINEDOR dose for your child based on age and the bodyweight.

Usage in Elderly:

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

Special Cases:

Kidney failure:

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

If you have advanced renal insufficiency or you are on dialysis treatment, your doctor will decide whether to use or not to use the medicine.

Liver failure:

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

Depending on the severity of your liver failure, your doctor will decide whether to use or not to use the medicine.

If you have an impression that the effect of LINEDOR is too strong or weak, talk to your doctor or pharmacist.

If you have more LINEDOR than you should:

If you think that the LINEDOR infusion given to you is too much, tell the doctor or nurse without waiting.

If you have missed a dose of LINEDOR

It is unlikely that a dose will be skipped, as the infusion of LINEDOR is administered by a doctor or nurse under supervision. However, if you think a dose of treatment has been skipped, tell the doctor or nurse immediately.

Effects that may arise after termination of treatment with LINEDOR

Consult your doctor about the use of this product.

4. Possible side effects

Like all medicines, side effects may occur in people sensitive to substances in the contents of LINEDOR.

If you notice any of these side effects during your treatment with LINEDOR, tell your doctor, nurse or pharmacist immediately.

- 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 LINEDOR.
- Problems with your vision such as blurred vision, changes in color vision, difficulty in seeing detail, if you have field of vision disorder.
- If you have diarrhea especially bloody diarrhea, your treatment may need to be discontinued. This may be the inflammation of the intestine that can occur following treatment with antibiotics.
- Recurrent nausea or vomiting, abdominal pain or over breathing.

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

Other side effects:

Side effects are listed as below categories:

Very Common: Can be seen in at least 1 out of 10 patients.

Common: Can be seen less than 1 of 10 patients, but more than 1 of 100 patients.

Uncommon: Can be seen less than 1 of 100 patients, but more than 1 of 1000 patients.

Rare: Less than 1 in 1000 patients can be seen.

Very rare: Less than 1 in 10.000 patients can be seen.

Not known: It cannot be estimated from the available data.

Common:

- Fungal infections especially vaginal or oral thrush
- Headache
- Metallic taste in the mouth
- Diarrhea, 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 anemia

Not common:

- Inflammation of the vagina or genital area in women
- Changes in numbers of certain cells in the blood which may affect your ability to fight infection
- Difficulty in sleeping
- Dizziness, sensations such as tingling or feeling numb
- Blurred vision
- Ringing in the ears (tinnitus)
- Increased blood pressure, inflammation of the veins
- Indigestion, stomach pain, constipation
- Dry or sore mouth, swollen, sore, or discolored tongue
- Skin redness
- Pain around the site of the vein
- Inflammation in the veins (including drop by drop infusion region)
- A need to urinate more often
- Fever or chills, aches and pains
- 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.
- Reduction in the numbers of cells in the blood, which fight against infection.

The following side effects have been observed to a lesser extent:

- Kidney failure
- Transient ischemic 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)
- 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, over-breathing)

- Severe skin disorders
- Convulsions

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

Reporting the side effects

If you get any side effects, which are mentioned or not mentioned in Package Insert, talk to your doctor, pharmacist or nurse. Moreover, report side effects that you have experienced to Turkey Pharmacovigilance Center (TÜFAM) by clicking icon "Reporting Side Effects" on the website www.titck.gov.tr or by calling 0 800 314 00 08, which is the line of Reporting Side Effects". By reporting side effects, you will contribute to learn more about the safety of the medicine you are using.

5. How to store LINEDOR

Keep LINEDOR out of reach and sight of children and in the original package.

Keep at room temperature below 25 °C, in a dry place and in the original package.

The vial should be used immediately after opening. Unused solution should be discarded.

Protect from freezing. LINEDOR solution for infusion can get a yellow color over time, but the benefit of the medicine is not adversely affected.

Use in accordance with expiration date.

Do not use LINEDOR after the expiration date on package.

Do not use LINEDOR if you notice distortions on the product and/or on the package.

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

Marketing Authorization Holder:

VEM İlaç San. ve Tic. A.Ş.

Söğütözü Mahallesi 2177.Cad. No:10 B/49

Çankaya/ANKARA/TURKEY

Manufacturing Site:

VEM İlaç San. ve Tic. A.Ş.

Çerkezköy Organize Sanayi Bölgesi

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