

PATIENT INFORMATION LEAFLET

MULTIFLEX LINEZOSEL 2 mg/mL I.V. Solution for Infusion, 300 mL

Sterile

Administered intravenously

- **Active ingredient:** Each mL infusion contains 2 mg linezolid.
- **Excipients:** Sodium citrate dihydrate, citric acid anhydrous, dextrose monohydrate (glucose), sodium hydroxide, hydrochloric acid, water for injections

Read all of this LEAFLET carefully before you are given 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.*
- *Please tell your doctor that you are taking this medicine when you go to the doctor or hospital during the use of this medicine.*
- *Please follow the instructions on this leaflet strictly. Do not use out of recommended (lower or higher) dose of this medicine.*

In this leaflet:

1. ***What is MULTIFLEX LINEZOSEL and what is it used for***
2. ***Before you are given MULTIFLEX LINEZOSEL***
3. ***How will you be given MULTIFLEX LINEZOSEL***
4. ***Possible side effects***
5. ***How to store MULTIFLEX LINEZOSEL***

Headings are provided.

1. What is MULTIFLEX LINEZOSEL and what is it used for?

- MULTIFLEX LINEZOSEL is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria that cause infections. It is used to treat pneumonia and some infections in the skin or under the skin.

- MULTIFLEX LINEZOSEL is a liquid administered slowly into a vein with the help of a plastic tube. This application is called intravenous infusion or drip. The active ingredient of MULTIFLEX LINEZOSEL, linezolid is an antibacterial agent.
- Disposable, ready-to-use two-outlet non-PVC (polyolefin) bags contain 300 ml (600 mg linezolid drug substance) solution and are packaged in heat sealed Al overpouch.

2. What you need to know before you are treated with MULTIFLEX LINEZOSEL

DO NOT have MULTIFLEX LINEZOSEL if,

- If you are allergic (hypersensitive) to linezolid or any of the other ingredients of this medicine listed above.
- 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 medications may be used to treat depression or Parkinson's disease.
- If you are breast-feeding. This is because this medicine passes into breast milk and could affect the baby.

MULTIFLEX LINEZOSEL may not be suitable for you if any of the following categories apply to you. 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.

- If you have high blood pressure, whether or not you are taking medicines for it,
- If you have been diagnosed with an overactive thyroid,
- If 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),
- If you suffer from manic depression, schizoaffective disorder, mental confusion or other mental problems,
- If you are 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,
- Sed to treat moderate to severe pain, such as pethidine,
- Medicines used to treat anxiety disorders, such as buspirone.
- An antibiotic called rifampicin

Use MULTIFLEX LINEZOSEL with caution in following situations

Tell your doctor before you are treated with MULTIFLEX LINEZOSEL if you:

- Bruise and bleed easily
- Are anaemic
- Are prone to getting infections
- Have a history of fit or 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.
- If there is loss of sensitivity in your arms or legs or a sensation of tingling or prickling in your arms or legs
- You may develop diarrhoea while taking or after taking antibiotics, including MULTIFLEX LINEZOSEL. If this becomes severe or persistent or you notice that your stool contains blood or mucus, you should stop taking MULTIFLEX LINEZOSEL 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. If these warnings apply to you even in the past please consult your doctor.

Having MULTIFLEX LINEZOSEL with food or drink

- You can take MULTIFLEX LINEZOSEL 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 MULTIFLEX LINEZOSEL 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

Consult your doctor or pharmacist before taking this medicine.

The effect of **MULTIFLEX LINEZOSEL** in pregnant women is not known. Therefore, it should not be taken 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 before taking this medicine. Consult your doctor about an effective birth control method during treatment

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

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

You should not breast-feed when taking MULTIFLEX LINEZOSEL because it passes into breast milk and could affect the baby.

Driving and using machines

MULTIFLEX LINEZOSEL 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.

Important information about some of the excipients of MULTIFLEX LINEZOSEL

This medicine contains glucose and sodium citrate as well as other excipients.

- This product contains 50.24 mg/mL. Please tell your doctor or nurse if you are diabetic. Use with caution for the patients who are diabetic.
- Each 1 mL of this product contains 0.38 mg sodium. Use with caution for the patients who are on a low sodium diet.

MULTIFLEX LINEZOSEL 2 mg/mL Solution for Infusion, 300 ml

Taking other medicines

There is a risk that MULTIFLEX LINEZOSEL 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.

MULTIFLEX LINEZOSEL medicines or have taken them recently. Must not be taken if you are already taking these

- 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 MULTIFLEX LINEZOSEL, 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.
- 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.

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including medicines obtained with or without prescription.

3. How you will be given MULTIFLEX LINEZOSEL

Instructions for the appropriate usage and dose / frequency of application:

The dose that will be administered, will be determined by your doctor based on your disease.

This medicine will be given to you through a drip (by infusion into a vein) by a doctor or healthcare professional. The usual 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 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 MULTIFLEX LINEZOSEL, your doctor should perform regular blood tests to monitor your blood count.

Your doctor should monitor your eyesight if you take MULTIFLEX LINEZOSEL for more than 28 days.

Administration route and method:

This medicine is given through a drip (by infusion into a vein).

Various age groups:

Use in children:

According to body weight and physical condition, the dose should be adjusted by your doctor.

Use in the elderly:

Your doctor will not make a dose adjustment for you.

Special conditions for use:

Renal failure:

Your doctor will not make a dose adjustment for you.

If you are on kidney dialysis, you should be given you medicine **after dialysis**.

Liver failure:

Your doctor will not make a dose adjustment for you.

Please talk to your doctor or pharmacist if you think that the effect of MULTIFLEX LINEZOSEL is too strong or too weak.

If you are given more MULTIFLEX LINEZOSEL than you should:

If you are concerned that you may have been given too much MULTIFLEX LINEZOSEL, tell your doctor or a nurse at once.

If you miss a dose of MULTIFLEX LINEZOSEL

Do not double the dose when you think that you have missed a dose of treatment

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.

Effects that may occur after MULTIFLEX LINEZOSEL treatment is stopped

Unless your doctor says to discontinue, continue your treatment with Multiflex LinezoseL. If main symptoms reoccurs after your treatment period completed, tell your doctor or pharmacist at once.

4. Possible side effects

Like all medicines, MULTIFLEX LINEZOSEL can cause side effects in people who are sensitive to one of the ingredients.

If you have one of the following, you should stop using the MULTIFLEX LINEZOSEL and tell your doctor IMMEDIATELY or please consult the nearest hospital's emergency department:

- 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 MULTIFLEX LINEZOSEL.
- 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 rare circumstances may develop into complications that are life-threatening. This situation may cause enteritis which may occur after antibiotic treatment.
- Recurrent nausea or vomiting, abdominal pain or rapid breathing.
- Fits or seizures have been reported with MULTIFLEX LINEZOSEL. You should let your doctor know if you experience agitation, confusion, delirium, rigidity, tremor, incoordination and seizure while also taking antidepressants known as SSRI's.

Numbness, tingling or blurred vision have been reported by patients who have been given MULTIFLEX LINEZOSEL 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 in below categories.

Very common : likely to occur in less than 1 in 10 people

Common : likely to occur in less than 1 in 10 people, but likely to occur in more than 1 in 100 people

Uncommon : likely to occur in less than 1 in 100 people, but likely to occur in more than 1 in 1000 people

Rare : may affect up to 1 in 1000 people but more than 1 in 10000 people

Very rare : affects less than 1 in 10000 people

Not known : frequency 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
- 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
- Hypertension
- Anemia (having low red blood cell count)
- Change in the number of certain cells in the blood that affect your fight against infection
- Skin rash

- Itching of the skin
- Drowsiness
- Regional or general abdominal pain
- Constipation
- Digestive difficulties
- Regional pain
- Fever

Uncommon:

- Inflammation in the vagina or genital area in women
- A decrease in the number of certain cells in the blood that affect your fight against infection
- Internal and external (vulvovaginal) disorders of the reproductive organ in women
- Sensitivity, such as tingling or numbness
- Blurred vision
- Ringing in the ear (tinnitus)
- Vascular inflammation
- Dry mouth or sore mouth, bloating, scar or tongue discoloration
- Need to urinate more often
- Tremors
- Feeling tired or thirsty
- Pancreatic inflammation
- Increased sweating
- Changes in proteins, salts, or enzymes in the blood that measure kidney and liver function
- Hives

- Gastric mucosa inflammation
- Soft stool
- Inflammation in the mouth
- Transfer (convulsion)
- Sodium level in the blood drops below normal (Hyponatremia)
- Kidney failure
- Decreased number of blood cells (platelets) that help the blood to clot
- Abdominal bloating
- Temporary ischemic crisis (temporary impairment of blood flow to the brain causes short-term symptoms such as loss of vision, weakness in the arms and legs, poor pronunciation and loss of consciousness)
- Pain at the injection site
- Inflammation of the skin
- Increased creatinine level
- Stomache ache
- Change in heart rhythm (such as increased rhythm)
- Decreased postprandial blood sugar

Rare:

- Limited vision, visual impairment
- Surface color changes in the tooth (It can be removed with professional tooth cleaning.)
- Bloody, watery diarrhea due to long-term use of antibiotics.
- Decreased defense cells and blood flakes with anemia (pancytopenia)

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

- Serotonin syndrome symptoms (rapid heartbeat, confusion, excessive sweating, inattention, sweating and tremor movements)
- Symptoms of lactic acidosis (recurrent vomiting and nausea, abdominal pain, rapid breathing)
- Severe skin disorders such as Stevens-Johnson Syndrome (inflammation with skin swelling and redness on the skin and around the eyes) and toxic epidermal necrolysis (a serious disease with fluid-filled blisters on the skin)
- Sideroblastic anemia (a type of anemia (low red blood cell count))
- Bone marrow suppression (myelosuppression)
- Very strong response of the body to allergy-causing substances, sudden hypersensitivity (anaphylaxis)
- Low blood sugar (Hypoglycaemia)
- Hair loss (Alopecia)
- Color changes in vision or difficulty in seeing details
- Decreased blood cell count
- Weakness and / or sensory changes
- Swelling of the face and throat as a result of allergies (angioedema)
- Damage to nerves that connect to the brain and spinal cord from other parts of the body (peripheral neuropathy)
- Visual nerve damage (optic neuropathy), inflammation of the visual nerves (optic neuritis), vision loss

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of suspected adverse reactions

If any side effects occur please talk to your doctor, pharmacist or nurse whether or not it is included in Patient Information Leaflet. You can also report suspected adverse reactions in accordance with local requirements. By reporting side effect you can help provide more information on the safety of this medicine.

5. How to store MULTIFLEX LINEZOSEL

Keep MULTIFLEX LINEZOSEL out of the reach and sight of children. Keep MULTIFLEX LINEZOSEL in the package.

Please use in accordance with expiration date.

Store it in its aluminum foil packing until time of usage.

This product should be used right after bag is opened. Unused solution should be discarded. Store at room temperature below 25°C. Protect from freezing.

MULTIFLEX LINEZOSEL may exhibit a yellow color that can intensify over time without adversely affecting potency.

Do not use MULTIFLEX LINEZOSEL after the expiry date which is stated on the package.

Marketing Authorization Holder: Haver Farma İlaç A.Ş.

Akbaba Mahallesi Maraş Cad. No:52/2/1
Beykoz/İstanbul
Tel: (0216) 324 38 38
Faks: (0216) 317 04 98

Manufacturing Site:

Osel İlaç San. ve Tic. A.Ş.
Akbaba Mah. Maraş Cad. No:52 34820
Beykoz/İstanbul
Tel: (0216) 320 45 50
Faks: (0216) 320 45 56

This leaflet was approved at 29/09/2017.