



PATIENT INFORMATION LEAFLET

LİNKOSOL 600mg /2 ml Solution for Injection Ampoule

For intramuscular and intravenous use

- **Active substance:** Each ampoule (2 ml) contains 600 mg lincomycin base (as lincomycin hydrochloride)
- **Other ingredients:** Benzyl alcohol, and water for injection

Read all this LEAFLET carefully before you start using this medicine, because there is important information for you in it.

- *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 recommend your medicine to others.*
- *If you submit to a doctor or hospital while using this medicine, tell about that you are using this medicine.*
- *Please strictly follow the instructions given in this leaflet. Do not use **higher or lower** dose that was recommended to you.*

In this leaflet:

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

1. What LİNKOSOL is and what it is used for

- LİNKOSOL, belongs to a group of medicines called lincosamide antibiotics.
- LİNKOSOL is an uncoloured clear solution in a glass ampoule. (1 or 100 ampoules)
- LİNKOSOL is used for the treatment of following infections sensitive to this antibiotic if your doctor prescribes to you:
 - Upper respiratory tract infections such as tonsillitis, pharyngitis, otitis media, and sinusitis.
 - Lower respiratory tract infections such as diphtheria, acute and contagious acute flaring of chronic bronchitis, lung infections.
 - Skin and soft tissue infections such as cellulitis (a non-necrotizing inflammation of the skin and subcutaneous tissues), furunculosis (deep infection of the hair follicle), abscess, impetigo (a bacterial skin infection that involves the superficial skin and very contagious, but not usually serious), infected wound, erysipelas (an acute infection typically with a skin rash, usually on any of the legs and toes, face, arms, and fingers), lymphadenitis (inflammation of a



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lymph node), paronychia (a soft tissue infection around a fingernail), mastitis (an infection of the breast tissue that results in breast pain, swelling, warmth and redness), and gangrene.

- Bone and joint infections such as osteomyelitis (an infection of bone), septic arthritis (the invasion of a joint by an infectious agent resulting in joint inflammation).

LİNKOSOL can also be used for more serious infections such as septicemia (a bacterial infection spread through the entire vascular system of the body) and endocarditis (a condition in which your heart's inner lining is inflamed).

2. Before you are given LİNKOSOL

DO NOT USE LİNKOSOL:

- If you are allergic to lincomycin or any of the other ingredients of this medicine.
- LİNKOSOL is not for use premature or term newborn babies.

Use LİNKOSOL with CAUTION in following circumstances:

- If you are experiencing diarrhea, if you have an history of antibiotic associated diarrhea or gastro-intestinal disease.
Inform your doctor immediately if you experience prolonged or bloody diarrhea while using this medicine; do not use any anti diarrhea pills without asking your doctor. This can be a sign of pseudomembranous colitis (an inflammation of the colon associated with an overgrowth of a specific bacterium most often related to recent antibiotic use) and you may need to cessation of your treatment.
- As other antibiotics, prolonged used of LİNKOSOL may lead to infections due to lincomycin-resistant bacteria and yeast infections (super infections). Symptoms of this condition can be oral or vaginal candidiasis. For this reason and for emergency treatment your treatment should be under the supervision of your doctor. Inform your doctor immediately if you experience pain or see white lesions at your mouth or tongue, itching or a discharge at your genital organs while using this medicine.
- In case of you have liver or kidney disease (To be sure this medication is not causing harmful effects; your blood may need to be tested on a regular basis. Your kidney or liver function may also need to be tested. Please do not miss to have these tests periodically).
- Patients with a stomach or intestinal disorder, especially colitis, LİNKOSOL should be used with caution.
- LİNKOSOL may increase the effects of muscle relaxants; therefore, patients using these medicines LİNKOSOL should be used with caution.
- LİNKOSOL should be used with caution in allergic patients.
- LİNKOSOL is not recommended for meningitis.
- In case of you have asthma or substantial allergy use LİNKOSOL with caution.



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If any of the above applies to you even if at the past, speak to your doctor before being given LĪNKOSOL.

Using LĪNKOSOL with food and drink

LĪNKOSOL can be given before or after meals as there is no interaction with food and drinks.

Pregnancy

Ask your doctor or pharmacist for advice before you are given LĪNKOSOL.

It is not known whether LĪNKOSOL usage during pregnancy is safe or not. Therefore, do not use LĪNKOSOL during pregnancy unless your doctor recommends.

If you became pregnant during your treatment immediately ask your doctor or pharmacist for advice.

Breast-feeding

Ask your doctor or pharmacist for advice before you are given LĪNKOSOL.

LĪNKOSOL can pass into breast milk. Therefore, do not use LĪNKOSOL during breast-feeding unless your doctor recommends.

Driving and Using machines

There is no special study evaluating the effects of LĪNKOSOL on driving and using machines. Although it is believed that LĪNKOSOL has no effect on driving and using machines, please consult your doctor in case of any related problem occurs.

Important information about some of the ingredients of LĪNKOSOL

Each LĪNKOSOL ampoule (2 ml) contains 18.9 mg of benzyl alcohol.

LĪNKOSOL should not be used in premature and term newborn babies. Benzyl alcohol may cause toxic and allergic reactions in children below 3 years of age.

Other medicines and LĪNKOSOL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

The following medicines can affect or be affected by treatment with LĪNKOSOL:

- Erytromycin (an antibiotic); both medicine decreases each other's effect.
- Muscle relaxants (LĪNKOSOL increases muscle relaxants' effects)
- Kaolin (a medicine used to treat diarrhea) can decrease the effect of LĪNKOSOL.



3. How LINKOSOL is given to you

Instructions for proper use and dosage/frequency of administration:

LINKOSOL will be given to you by a doctor or nurse.

Your medicine will be given to you by injection into a muscle (intramuscularly) or into a vein (intravenously). Your doctor will decide how much you need each day and how often the injections should be given.

To treat severe infections the usual adult doses are:

- by intramuscular injection: 600 mg (1 ampoule) every 24 hours.
- by intravenous injection: 600 - 1000 mg every 8 to 12 hours

This dose can be increased in case of more severe infections.

Follow strictly your doctor's recommendations and never make dosage changes yourself.

Administration route and method:

Your medicine will be given to you by injection into a muscle (intramuscularly) or into a vein (intravenously).

Usage in different age groups:

Children:

Your doctor will decide how much you need each day and how often the injections should be given.

Elderly:

Your doctor will decide how much you need each day and how often the injections should be given.

Usage in special conditions:

Patients with kidney problems:

Your doctor will decide how much you need each day and how often the injections should be given.

Patients with liver problems:

Your doctor will decide how much you need each day and how often the injections should be given.



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If you think the effect of LINKOSOL is too much or weak, talk to your doctor or pharmacist.

If you are given too much LINKOSOL:

This medicine is given to you by a doctor or a nurse. It is unlikely that you will be given too much.

If you think you have been given too much LINKOSOL speak to your doctor immediately or submit to the nearest emergency service of a hospital.

If you think you have missed a dose of LINKOSOL:

If you think that a dose of LINKOSOL has been missed, tell your doctor.

Do not use double dose to compensate missed doses.

When you stop taking LINKOSOL:

Please use regularly and strictly follow your doctor's recommendations.

Do not stop treatment even if you feel better; early termination of treatment with antibiotics may result incomplete bacteria kill and recurrence of your infection.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking LINKOSOL and tell your doctor straight away or submit an emergency clinic of the nearest hospital if you notice any of the following side effects:

- Sudden sneezing attacks, breathing difficulties, swelling of the face, eyelids, and lips, skin rash or itching (especially affecting whole body)

These are serious side effects. If you have one of these side effects, these means that you have a serious allergy to LINKOSOL. You may need urgent medical treatment or hospitalized. These serious side effects are very rare.

Tell your doctor straight away or submit an emergency clinic of the nearest hospital if you notice any of the following side effects:

- Uncommon but serious prolonged or bloody diarrhea (can be accompanied with severe abdominal cramps and fever). This side effect occurring during or after the antibiotic treatment may be a sign of a serious infection of intestines.
- Thrush (a yeast infection of the vagina or mouth)
- Icterus (yellowing of the skin and the whites of the eyes)
- An excessive breakdown of blood cells causing bruises, bleeding or weakness in your



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immune system.

- Extensive peeled and swollen areas on skin.
- Cardiac (related with heart) symptoms.

These are serious side effects. You may need urgent medical treatment. These serious side effects are very rare.

Tell your doctor if you notice any of the following side effects:

- Disturbances in taste sense.
- Skin redness, itching or rash.
- Ulcerations at the esophagus (gullet), throat pain.
- Feeling sick (nausea).
- Vomiting.
- Pain at the stomach.
- Decreasing in your liver enzyme levels (shown in blood tests).
- Induration, irritation or abscess formation at the injection site.
- Tinnitus (ringing in the ears).
- Dizziness.

These are mild side effects of LINKOSOL.

Other side effects

If you have any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store LINKOSOL

Keep this medicine out of the sight and reach of children.

Store below 30°C at room temperature.

Use consistent with expiry date.

Do not use LINKOSOL after the expiry date which is stated on the label.



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Marketing Authorization Holder and Manufacturer:

Osel İlaç San. ve Tic. A.Ş.

Akbaba Mah. Maras Cad. No: 52

Beykoz / İSTANBUL/TURKEY

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