

## KULLANMA TALİMATI

### **GENTHAVER 80 mg /2 mL IM/IV Solution for Infusion**

**Sterile**

**Administered intramuscular or intravenously.**

- **Active substance:** Each ampoule (2 mL) contains 135,59 mg gentamicin sulphate equivalent to 80 mg gentamicin.
- **Excipients:** methyl paraben (E218), propyl paraben (E216), sodium metabisulfite (E223), Disodium EDTA, sodium hydroxide (pH adjustment) and water for injection.

**Read all of this leaflet carefully before you start using 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.*
- *Tell your doctor that you are taking this medicine when you go to the doctor or hospital during the use of this medicine.*
- *Follow exactly what is written in this instruction. Do not use high or low doses other than the recommended dosage.*

#### **What is in this leaflet:**

1. *What GENTHAVER is and what it is used for?*
2. *What you need to know before you use GENTHAVER ?*
3. *How to use GENTHAVER?*
4. *What are the possible side effects?*
5. *How to store GENTHAVER*

**Headings are included.**

#### **1. What GENTHAVER is and what it is used for?**

- GENTHAVER, is presenting in an ampoule containing a particle-free, colorless, clear solution with the active ingredient gentamicin (as gentamicin sulfate).
- GENTHAVER is an aminoglycoside group antibiotic.
- It is available in packagings that each box contains 1, 5,50 or 100 pcs 2 mL ampoules..

GENTHAVER is used for the treatment of a wide variety of infections such as breast, wound and blood infections.

## **2. What you need to know before you use GENTHAVER**

Carefully follow all instructions given by your doctor or pharmacist.

### **DO NOT USE GENTHAVER;**

If,

- You are allergic to gentamicin, sodium metabisulfite (E223), methyl paraben (E218) and propyl paraben (E216) or any of the other components of GENTHAVER,
- You have Myasthenia Gravis (a disease that causes muscle weakness).

### **USE GENTHAVER CAREFULLY**

- In the treatment of premature babies,
- You are an elderly patient,
- Your kidneys are not fully functioning,
- You have diabetes,
- You have an ear problem, hearing or balance disorder, if you have had ear infections, or have been treated with antibiotics that affect hearing in the past,

If these warnings apply to you, even at any time in the past, please consult your doctor.

### **Use of GENTHAVER with food and drink**

Not applicable.

### **Pregnancy**

*Consult your doctor or pharmacy before using the medicine.*

If you are pregnant or if you think you might be pregnant, please tell your doctor. You should not use GENTHAVER during pregnancy unless your doctor deems it necessary.

### **Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*

If you are breastfeeding your baby, tell your doctor.

Gentamicin passes into breast milk. Therefore, if you are taking GENTHAVER, you should not breast-feed your baby, or do not use GENTHAVER while breastfeeding, as this may be harmful to your baby.

### **Driving and using machines**

If you experience an effect that affects your ability to drive and use machines, do not drive or use machines.

### **Important information about some excipients found in the composition of GENTHAVER**

GENTHAVER contains sodium metabisulfite (E223). Rarely, severe hypersensitivity reactions and narrowing of the bronchi can have effect.

GENTHAVER contains methyl paraben (E218) ve propyl paraben (E216). Rarely, it may cause allergic reactions (possibly delayed) and extraordinary constriction of the bronchi.

This medicinal product contains less than 1 mmol (23 mg) of sodium at a dose of 80 mg / 2 mL; that is, sodium free.

### **Use with other medicines**

It is especially important that you tell your doctor if you are taking any of the following medications:

- Other aminoglycosides, cephalotin, methicillin, drugs that affect your kidneys or hearing,
- Blood thinners (such as warfarin and fenindion), which are called oral anticoagulants (drugs used to prevent blood clotting),
- Amphotericin (a drug used in the treatment of fungal infections),
- Neostigmine and pyridostigmine (drugs used to treat muscle weakness),
- Cyclosporine (a drug that reduces the activity of the immune system, especially used in organ transplant patients),
- Cisplatin (a drug used to treat cancer),
- Some diuretics, such as ethacrynic acid and furosemide,
- Muscle relaxants used during general anesthesia (such as tubocurarin and succinyl choline),
- Botulinum toksini,
- With bisphosphonates (drugs used to treat osteoporosis).

*If you are using or have recently used any type of prescription or non-prescription drugs, please inform your physician or your pharmacist.*

### **3. How to use GENTHAVER**

#### **Instructions for appropriate use and dose / administration frequency:**

The dose of GENTHAVER will be determined by your doctor based on the severity of your infection, your age, your body weight and the operating status of your kidneys.

GENTHAVER is usually administered intramuscularly, but in some patients it can also be administered intravenously.

In adults with normal renal function, the daily dose is 3-6 mg/ kg administered in one or two separate doses.

The amount of gentamicin in your blood will be measured regularly to ensure proper blood levels are maintained. Gentamicin treatment may cause hearing and renal dysfunction.

In some cases, your doctor may ask you to have a blood test before and during treatment to assess your kidney function. Sometimes you may be asked to have a hearing test to see if the medicine affects your hearing.

**Method of administration:**

If it is to be administered intravenously, it can be injected directly into the vein or dissolved in serum or 5% glucose solution and administered by slow infusion. However, GENTHAVER is usually administered “intramuscularly”.

**Various age groups:**

**Use in Children:**

Children (1 year and older) and adolescents; the recommended dose is 3-6 mg/kg administered in one or two doses per day.

In infants between 1 month and 1 year; The daily dose is 4.5-7.5 mg/kg administered in one or two doses.

In infants up to 1 month; the recommended dose is 4.5-7.5 mg/kg as a single dose per day.

**Use in Elderly:**

Elderly patients may be more sensitive to the effects of GENTHAVER than other adults. Therefore, in elderly patients, during gentamicin treatment, blood tests should be performed to monitor blood drug levels and renal function and hearing should be evaluated with hearing tests.

*Talk to your doctor or pharmacist if you have the impression that the effect of GENTHAVER is too strong or weak.*

**If you have used more GENTHAVER than you should**

Since GENTHAVER will be administered by your doctor or nurse, the possibility of overdosing is very low. However, if in doubt, ask your doctor or nurse.

*If you have used more than you should use from GENTHAVER, talk to a doctor or pharmacist.*

**If you forget to use GENTHAVER**

This is unlikely since GENTHAVER will be administered by a doctor or nurse.

**Effects which may occur when treatment with GENTHAVER is discontinued**

Do not discontinue treatment other than by your doctor. If you experience a problem while using the medicine, consult your doctor.

**4. What are the possible side effects?**

Like all medicines, people who are sensitive to the ingredients of GENTHAVER may have side effects.

Very common	: It can be seen in at least one in 10 patients.
Common	: It can be seen in less than 1 in 10 patients, but in more than 1 in 100 patients.
Uncommon	: It may occur in less than 1 in 100 patients, but in more than 1 in 1,000 patients..
Rare	: It may occur in less than 1 in 1,000 patients but in more than 1 in 10,000 patients.
Very rare	: It can be seen in less than 1 in 10,000 patients.
Unknown	: Cannot be predicted based on available data.

**Stop using GENTHAVER and notify your doctor IMMEDIATELY if any of the following occurs, or contact the emergency department of your nearest hospital:**

- Serious allergic reaction - sudden itching rash (hives), swelling of hands, feet, wrists, face, lips, mouth or throat (which may make it difficult to swallow or breathe) and feel faint.

These are very serious side effects.

If you have one of these symptoms, you have serious allergies to GENTHAVER. You may need urgent medical attention or hospitalization.

**If you notice any of the following, notify your doctor immediately or contact the emergency department of your nearest hospital:**

**Common:**

- Any abnormalities you experience when you urinate (blood in your urine or urinating less than usual; these symptoms may mean there is a problem with your kidneys).

**Uncommon:**

- Dark fluffy spots that may be skin rash (hives) or itchy
- Difficulty breathing

**Rare:**

- Bloody diarrhea with abdominal pain and cramps

**Very rare**

- Confusion
- Unrealistic images or sounds (hallucinations)
- Balance disorder, feeling dizzy
- Muscle weakness (if you are having difficulty moving or feeling tired)

**Unknown:**

- Hearing problems (if you experience this side effect, your doctor may reduce the dose of your medication or change your medication.)

All these are serious side effects. Immediate medical attention may be required.

**Inform your doctor if you notice any of the following:****Uncommon:**

- Feeling sick or being sick (nausea and vomiting)
- Injuries to the mouth

**Very Rare:**

- Depression

**Unknown:**

- Fever
- Sore throat

These are mild side effects of GENTHAVER.

*If you experience any side effects not mentioned in this instruction manual, inform your doctor or pharmacist.*

**Reporting of suspected adverse reactions**

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 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 GENTHAVER**

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

Store at room temperature below 30°C.

Store in its original packaging.

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

*Do not use GENTHAVER after the expiration date stated on the packaging.*

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

### ***Marketing Authorization Holder:***

OSEL İlaç San. ve Tic. A.Ş.  
Akbaba Mah. Maraş Cad. No.:52  
Beykoz/İSTANBUL

### ***Manufacturing Site:***

OSEL İlaç San. ve Tic. A.Ş.  
Akbaba Mah. Maraş Cad. No.:52  
Beykoz/İSTANBUL

*This patient information leaflet was approved on 30/04/2023.*

FOLLOWING INFORMATION IS FOR HEALTH PROFESSIONAL TO ADMINISTER THIS MEDICINE

Instructions for use of the human product and disposal of unused product or waste materials:

The recommended dose can be dissolved in 100 mL of 0.9% NaCl or 5% glucose solution, but should not be dissolved in solutions containing bicarbonate. The prepared solution should be infused for 20 to 30 minutes.

Used products or waste materials must be disposed of in accordance with the “Medical Waste Control Regulation” and “Packaging and Packaging Waste Control Regulations”.