

UROMUNE®



**300 FTU/mL (10⁹ bacteria/mL),
suspension for sublingual
administration**

Inactivated and selected non-lysate
bacterial strains

**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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What UROMUNE is and what it is used for
2. What you need to know before you use UROMUNE
3. How to use UROMUNE
4. Possible side effects
5. How to store UROMUNE
6. Contents of the pack and other information

1. What UROMUNE is and what it is used for

UROMUNE is a glycerinated suspension containing four inactivated and selected non-lysate bacterial strains (10⁹ Bacteria/mL), intended for specific sublingual immunotherapy. Its composition and concentration are listed on the box labels, vials and section 6 of this leaflet.

UROMUNE is a mucosal immunotherapy indicated for the prevention of urinary tract infections caused by different pathogens. It works by stimulating the immune system, thus increasing the resistance against recurrent infections.

UROMUNE can be used in adult and pediatric patients. See section 2. Children.

2. What you need to know before you use UROMUNE

Do not use UROMUNE

- If you are allergic to any of the ingredients of UROMUNE (listed in section 6).

If you are not sure whether you should use this medicine, contact your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using UROMUNE.

Children

Based on previous clinical experience, UROMUNE can be used in children and infants. Doses are identical in adults and pediatric patients.

Other medicines and UROMUNE®

No drug interaction has been described with other medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

UROMUNE with food and drink

UROMUNE must be administered as separate as possible from the intake of food and drinks (at least, 30 minutes after the consumption of food and/or drink). Do not brush your teeth or rinse the mouth within the 30 minutes of administration.

Pregnancy and breast-feeding

There are not specific studies addressing the use of UROMUNE in pregnant or breast-feeding women, although its use is not formally contraindicated. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

UROMUNE has no influence on the ability to drive and use machines.

3. How to use UROMUNE

Always use this medicine exactly as described in this leaflet or as your doctor has told you.

The appropriate dosage and duration will be established by your doctor.

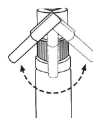
Do not change the dose of the medicine without consulting your doctor. Check with your doctor if you are not sure how to use this medicine.

The recommended dose for this medicine is 2 sprays per day (2 sprays is one dose).

Instructions for use

UROMUNE is administered sublingually.

1. Remove the plastic seal from one vial.
2. Gently shake the vial.
3. Rotate the nozzle sideways. Spray 3 or 4 times to ensure the correct filling of the dispenser (only when starting the vial).



4. Lift your tongue, direct the nozzle under your tongue and spray twice to apply the appropriate dose.



5. Hold the liquid under your tongue, without swallowing for approximately 2 minutes and then swallow.
6. Rotate the nozzle back to its downward pointing position.
7. Return the vial back to the box and store accordingly as referenced in section 5.

When the first vial is finished, continue immediately to the second one with the same dose (2 daily sprays).

The duration of each vial is approximately 45 days at the recommended dose. The course of this treatment is 90 days, approximately.

If you use more UROMUNE than you should

It is important to use UROMUNE as instructed. If you spray too many times, take the next dose as scheduled.

No case of overdose is known up to now. Due to the nature of UROMUNE, an overdosage seems unlikely to happen.

You may experience some of the common side effects (see section 4). If you experience any side effect, inform your doctor or pharmacist.

If you forget to use UROMUNE

If you forget to use UROMUNE, use it as soon as possible. However, if it is almost time for your next dose, skip the missed one and go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

If you stop using UROMUNE

If you do not use UROMUNE as indicated, clinical benefits may be lower than expected.

If you want to stop using this medicine, talk to your doctor first. Do not stop the treatment without consulting your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

You can usually carry on taking UROMUNE, unless the effects are serious. If you are worried, talk to your doctor or pharmacist. Do not stop using UROMUNE without speaking to your doctor.

At the beginning of your treatment, you may exceptionally experience a mild heat sensation and/or discomfort in your mouth. Experiencing local adverse reactions does not imply that treatment should be discontinued, but you may need further instructions on how to take UROMUNE from your doctor or pharmacist.

You may also exceptionally experience slight disturbances of the gastrointestinal tract and/or mucosal inflammatory reaction.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store UROMUNE

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

Do not use this medicine after the expiry date which is stated on the box and vials after EXP. The expiry date refers to the last day of that month.

Store in the original packaging in order to protect it from light.

Store between 2-8°C. Keep refrigerated.

This medicine can be transported and/or stored at room temperature (< 25°C) for a short time (6 - 12 hours).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What UROMUNE contains

- The active substances are 4 inactivated and selected non-lysate bacterial strains:

- *Klebsiella pneumoniae* 25%
- *Escherichia coli* 25%
- *Enterococcus faecalis* 25%
- *Proteus vulgaris* 25%

Each mL of the product contains 300 FTU or Formazin Turbidity Units (10⁹ bacteria).

- The other excipients are glycerol, artificial pineapple flavouring, sodium chloride and water for injection.

What UROMUNE looks like and contents of the pack

UROMUNE is a colourless glycerinated suspension packed in 2 x 9 mL amber glass vials containing a spray pump and a nozzle.

Distributor

For any information about this medicine, please contact the local distributor.

Manufacturer

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