

# Uromune 300 FTU sublingual spray, suspension

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Uromune?

Uromune contains four inactivated whole-cell bacterial strains as active ingredients. Uromune is used for the prevention of recurrent urinary tract infections.

For more information, see Section [1. Why am I using Uromune?](#) in the full CMI.

### 2. What should I know before I use Uromune?

Do not use if you have ever had an allergic reaction to Uromune or any of the ingredients of this medicine listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Uromune?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Uromune and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Uromune?

- The recommended dose is 2 sprays (0.1 mL approx. for each spray) administered daily sublingually. 2 sprays constitute one dose.
- Always take this medicine as described in this leaflet or as your doctor has told you. Check with your doctor if you are not sure.

More instructions can be found in Section [4. How do I use Uromune?](#) in the full CMI.

### 5. What should I know while using Uromune?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Uromune.</li><li>• Uromune must be administered as separate as possible from taking food and drinks.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop the treatment without consulting your doctor.</li><li>• Do not take food and/or drink, brush your teeth or rinse the mouth within the 5-10 minutes prior or after administration.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Uromune has no or negligible influence on the ability to drive and use machines.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store in a refrigerator (2 °C - 8 °C).</li><li>• Keep this medicine out of the sight and reach of children.</li></ul>

For more information, see Section [5. What should I know while using Uromune?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects: oral pruritus. Uncommon side effects: oral pain, epigastric discomfort, dry mouth, pruritus, and malaise. Rare side effects: decreased appetite, headache, paraesthesia, eye irritation, eyelid rash; flushing, upper-airway cough syndrome; gastritis, glossitis, abdominal discomfort, diarrhoea, vomiting, abdominal pain, nausea, gastroesophageal reflux disease, oral discomfort, dental discomfort, tongue discomfort, dyspepsia, paraesthesia oral, rash, arthralgia, fatigue, chest discomfort, generalised oedema, and pain. Serious side effects: asthma or asthma aggravated. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Uromune 300 FTU sublingual spray, suspension

**Active ingredient(s):** *Whole-cell inactivated bacterial strains*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Uromune. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Uromune.**

**Where to find information in this leaflet:**

1. Why am I using Uromune?
2. What should I know before I use Uromune?
3. What if I am taking other medicines?
4. How do I use Uromune?
5. What should I know while using Uromune?
6. Are there any side effects?
7. Product details

### 1. Why am I using Uromune?

Uromune contains four inactivated whole-cell bacterial strains as active ingredients: *Escherichia coli*, strain V121, inactivated (25%), *Klebsiella pneumoniae*, strain V113, inactivated (25%), *Enterococcus faecalis*, strain V125, inactivated (25%) and *Proteus vulgaris*, strain V127, inactivated (25%).

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

**Uromune is used for the prevention of recurrent urinary tract infections.**

### 2. What should I know before I use Uromune?

#### Warnings

**Do not use Uromune if:**

- you are allergic to the active ingredients, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- have any other medical conditions.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

#### Important information about some of the ingredients of Uromune

- Uromune contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially "sodium-free".

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Uromune and affect how it works.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Uromune.**

### 4. How do I use Uromune?

Always take this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor if you are not sure.

#### How much to take / use

- The recommended dose is 2 sprays (0.1 mL approx. for each spray) administered daily sublingually. 2 sprays constitute one dose.
- Follow the instructions provided and use Uromune until your doctor tells you to stop.

#### How to use Uromune

Uromune is administered through the sublingual route.

1. Remove the plastic seal from one bottle.
2. Gently shake the bottle.

3. Rotate the nozzle sideways: **ATTENTION, DO NOT LIFT THE NOZZLE FORWARD.** Only when starting a new bottle: Press the spray button 3 or 4 times to ensure the pump mechanism fills up. You will not need to do this again until you start a new bottle.



4. Lift your tongue, direct the nozzle under your tongue, and spray twice to apply the appropriate dose. Press the center of the actuator firmly and fully in one continuous motion.



5. Retain the dose under your tongue, for approximately 1-2 minutes before swallowing.  
6. After administration, rinse the nozzle to prevent product blockage during the next administration. Rotate the nozzle back to its original vertical position, thereby locking the spray mechanism.  
7. Return the bottle back to the box and store accordingly as referenced in section 5.

When the first bottle is finished, the administration should be continued with the second one, maintaining the same schedule (2 daily sprays). The duration of the treatment package is approximately 3 months (approx. 45 days per bottle). This duration is approximate; it can vary as the administration is performed by the patient themselves.

#### Use in children

The safety and efficacy of Uromune in children has not been established.

#### If you forget to use Uromune

If you forget to take Uromune, take it as soon as possible.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

#### If you use too much Uromune

If you spray too many times, take the next dose as scheduled. You may experience some of the common side effects (see

section 6). If you experience any of these side effects inform your doctor or pharmacist.

#### Further help can be obtained by:

- phoning the Poisons Information Centre (by calling 13 11 26), or
- contacting your doctor, or
- go to the Emergency Department at your nearest hospital if symptoms worsen
- If an emergency, call 000 (Australia) or 111 (New Zealand)

### 5. What should I know while using Uromune?

#### Things you should do

##### Call your doctor straight away if you:

- notice any sudden and remarkable symptoms of urticaria, rash, itching (especially affecting your whole body) that could be signs of an allergic reaction to this medication.

Remind any doctor, dentist or pharmacist you visit that you are using Uromune.

##### Things you should not do

- Do not stop using this medicine suddenly without consulting your doctor.
- Do not take food and/or drink, brush your teeth or rinse the mouth within the 5-10 minutes prior or after administration.

#### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Uromune affects you.**

Uromune has no or negligible influence on the ability to drive and use machines.

#### Drinking alcohol

**Tell your doctor if you drink alcohol.**

#### Looking after your medicine

- Store in a refrigerator (2°C - 8°C).

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

#### When to discard your medicine

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

#### Disposing of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

#### Less serious side effects

Less serious side effects	What to do
<p><b>Metabolism and nutrition disorders:</b></p> <ul style="list-style-type: none"> <li>• Decreased appetite</li> </ul> <p><b>Nervous disorders:</b></p> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Paraesthesia</li> </ul> <p><b>Eye:</b></p> <ul style="list-style-type: none"> <li>• Eye irritation</li> <li>• Eyelid rash</li> </ul> <p><b>Vascular:</b></p> <ul style="list-style-type: none"> <li>• Flushing</li> </ul> <p><b>Respiratory:</b></p> <ul style="list-style-type: none"> <li>• Upper-airway cough syndrome</li> </ul> <p><b>Gastrointestinal:</b></p> <ul style="list-style-type: none"> <li>• Oral pruritus</li> <li>• Oral pain</li> <li>• Epigastric discomfort</li> <li>• Dry mouth</li> <li>• Gastritis</li> <li>• Glossitis</li> <li>• Abdominal discomfort</li> <li>• Diarrhoea</li> <li>• Vomiting</li> <li>• Abdominal pain</li> <li>• Nausea</li> <li>• Gastroesophageal reflux disease</li> </ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"> <li>• Oral discomfort</li> <li>• Dental discomfort</li> <li>• Tongue discomfort</li> <li>• Dyspepsia</li> <li>• Paraesthesia oral</li> </ul> <p><b>Pruritus</b></p> <ul style="list-style-type: none"> <li>• Rash</li> </ul> <p><b>Musculoskeletal disorders:</b></p> <ul style="list-style-type: none"> <li>• Arthralgia</li> </ul> <p><b>Others:</b></p> <ul style="list-style-type: none"> <li>• Malaise</li> <li>• Fatigue</li> <li>• Chest discomfort</li> <li>• Generalized oedema</li> <li>• Pain</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Respiratory:</b></p> <ul style="list-style-type: none"> <li>• Asthma</li> <li>• Asthma aggravated</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. In an emergency call 000 (Australia) or 111 (New Zealand).</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

#### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online (Australia) at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) or Medsafe (New Zealand) [www.medsafe.govt.nz/safety/report-a-problem.asp](http://www.medsafe.govt.nz/safety/report-a-problem.asp).

By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

### 7. Product details

This medicine is only available with a doctor's prescription.

#### What Uromune contains

<p><b>Active ingredient (main ingredient)</b></p>	<p>4 inactivated whole-cell bacterial strains: <i>Escherichia coli</i>, strain V121, inactivated (25%), <i>Klebsiella pneumoniae</i>, strain V113, inactivated (25%), <i>Enterococcus faecalis</i>, strain V125, inactivated (25%) and <i>Proteus vulgaris</i>, strain V127, inactivated (25%).</p>
<p><b>Other ingredients (inactive ingredients)</b></p>	<p>glycerol (E-422), sodium chloride, artificial pineapple flavoring (containing propylene glycol) and water for injection</p>

**Do not take this medicine if you are allergic to any of these ingredients.**

#### What Uromune looks like

Uromune is presented as a suspension presented in a type III amber glass bottle, closed with a white plastic rotary applicator with an integrated spray inserted (nozzle).

Uromune is available in packs of 2 bottles, each one containing 9 mL of product.

#### Who distributes Uromune

##### Sponsor in Australia:

Inmunotek Australia Pty Ltd  
L13/99 Walker st  
North Sydney  
2060 NSW

Email: [info@immunotek.com.au](mailto:info@immunotek.com.au)  
Phone: 1300 706 908

##### Sponsor in New Zealand:

Inmunotek New Zealand Ltd  
Level 8, 139 Quay st  
Auckland 1010  
Email: [info@immunotek.co.nz](mailto:info@immunotek.co.nz)  
Phone: 09 302 0668

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