

# UROMUNE®

## PERLINGUAL SPRAY

(Urinary tract infection immunostimulant)  
2 x 9ml spray Bottles

### Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again
- If you have further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours
- If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

### In this leaflet

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### 1. What is **UROMUNE®** used for

**UROMUNE®** is an oral immunostimulant for the prevention of urinary tract infections. It works by stimulating the immune system by increasing the resistance against urinary tract infections.

- **UROMUNE®** is prescribed for **preventing urinary tract infections**, on a case-by-case basis

**UROMUNE®** is a medical product containing inactivated bacterial suspension for sublingual immunotherapy (perlingual). Its composition and concentration are listed on the box, vial and in section 6 of this leaflet.

### 2. Before you use **UROMUNE®**

#### Do Not use **UROMUNE®**

- If you are allergic (hypersensitive to any of the ingredients in **UROMUNE®** listed in section 6

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

### Use in children

**UROMUNE®** can be used in children and breastfed babies.

### Using other medicines

Tell your doctor or pharmacist if you are taking any other medicines or have recently taken any. This includes medicines obtained without a prescription.

### 3. How to use **UROMUNE®**

Always use **UROMUNE®** exactly as your doctor has told you. You should check with your doctor if you are not sure how to use this medicine. The appropriate dosage and duration will be established by your doctor.

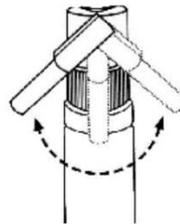
Do not change the dose of the medicine without consulting your doctor.

**Recommended dose for this medicine is 2 sprays per day (2 sprays is one dose)**

#### Instructions for use

**UROMUNE®** is administered sublingually (perlingual).

1. Remove the plastic seal from one bottle
2. Gently shake the bottle
3. Rotate the nozzle sideways



4. Lift your tongue and 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 then swallow
6. Rotate the nozzle back to its downward pointing position
7. Return the bottle to the box and store accordingly referenced in section 5

When the first bottle is finished, continue immediately: to the second with the same dose (2 sprays).

The duration of each bottle is approximately 45 days at the recommended dose.

The course of this treatment is approximately 90 days.

### **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. You may experience some of the common side effects of a mild heat sensation, swelling or itching in your mouth. If you experience any uncommon side effects 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.

### **If you stop using UROMUNE®**

If you want to stop using this medicine talk to your doctor first. If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, **UROMUNE®** 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 start of your treatment you may, exceptionally, experience a mild heat sensation, swelling or itching in your mouth. You may need further instruction on how to take **UROMUNE®** from your doctor or pharmacist.

You may also, exceptionally, experience slight disturbances of the gastro-intestinal tract and/or mucosal inflammatory reaction.. If you experience any of these inform your doctor or pharmacist.

## **5. How to store UROMUNE®**

Keep out of sight and reach of children.

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 the month.

Store in original packaging in order to protect from light.

Store between 2 - 8°C Keep refrigerated

### **Do not freeze**

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

## **6. Further Information**

### **How does UROMUNE® look like**

**UROMUNE®** is a colourless liquid contained in 2 x 9mL bottles with a spray nozzle.

### **What UROMUNE® contains**

**UROMUNE®** contains 4 deactivated bacteria. Each bottle of 9 mL contains 10<sup>9</sup> Bacteria/mL

*Klebsiella pneumoniae* 25%

*Escherichia coli* 25%

*Enterococcus. faecalis* 25%

*Proteus vulgaris* 25%

**Excipients:** glycerol, pineapple essence, sodium chloride and water for injection.

### **Distributor:**

For product information, Adverse Events and product complaints within the UK, please contact:

#### **Syner-Med (PP) Ltd**

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### **Manufacturer:**

#### **INMUNOTEK, S.L.**

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### **Uromune®**

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