

Uromune: prescribing guide

What is it?

Uromune is a mucosal vaccine used for the prevention of urinary tract infections. It is an unlicensed product in the UK but has been endorsed for use by specialist teams (urology, urogynaecology and microbiology) within Swansea Bay by the Heath Board Medicines Management Board.

How does it work?

It works by stimulating the immune system to reduce the development of urinary tract infections. This is achieved via daily exposure to inactivated bacteria that commonly cause urine infections i.e. *Klebsiella pneumonia*, *E.coli*, *E.faecalis* and *Proteus vulgaris*. This protective effect lasts for up to 1 -2 years following a 3 month course.

Which patients should I consider prescribing uromune in?

Uromune is reserved for adult patients with who have not responded to treatment for recurrent UTIs, including all conventional measures recommended in the [antimicrobial guidelines](#) e.g. prophylactic antibiotics, methenamine. It can only be prescribed by specialist teams within the hospitals i.e. consultant urologist, consultant urogynaecologist and consultant microbiologists.

How do I prescribe it?

Prescribe as Uromune perlingual spray; the recommended dose is 2 sprays, under the tongue, once per day.

The recommended treatment course is 3 months.

Each original pack contains two bottles and provides enough supply for 3 months. Supplies are available in the hospital pharmacies in Singleton and Neath Port Talbot hospitals.

What else do I need to consider before prescribing?

There are no or limited amount of data from the use of Uromune in pregnant women or for breastfeeding. No interaction studies have been performed.

What do I need to tell the patient?

Patients should be made aware of the unlicensed nature of this product.

A patient information leaflet is included in appendix one with instructions for administration

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

The product needs to be stored in a refrigerator.

Side effects occur with a low frequency and include allergic response to components (with respiratory and skin reactions), mild swelling / itching in mouth with mucosal inflammation. GI disturbances. Rarely systemic side effects e.g. malaise, rash and generalised pruritus can occur.

References



1.-Uromune® -SPC.
pdf



Uromune PIL.pdf



Uromune - Review
of Studies.docx

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 or other healthcare professional
- 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

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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 **treating urinary tract infections**. It can be used when you have a urinary tract infection
- Uromune can also be prescribed for **preventing urinary tract infections**, on a

case-by-case basis – for example if you have experienced recurring urinary tract infections

Uromune is a medical product containing inactivated bacterial suspension for oral 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 is not for use in children under 2 years.

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 orally.

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 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're 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 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 experience slight disturbances of the gastro-intestinal tract and in very rare incidences you may possibly experience mucosal inflammatory reaction, difficulty breathing, or an allergic skin 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

What 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. 2 x 9ml 10x9B/ml

Klebsiella pneumoniae 25%

Escherichia coli 25%

E. 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

Syner-Med House

120 High Street

Purley

Surry

CR8 2AD

UK

Phone: +44(0)208 655 6380

Fax: +44(0)208 655 6398

Website: www.syner-med.com

Manufacturer:

INMUNOTEK, S.L.
Calle Punto Mobi 5,
28805 Alcalá de Henares,
Madrid, España.
Tel: +34 912 908 942
Fax: +34 902 906 841
www.inmunotek.com

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