

## **Steps in obtaining Uromune with TGA approval shared by an Australian member of the chronic UTI community**

Inmunotek website: [www.inmunotek.com](http://www.inmunotek.com)

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### Seeking TGA approval:

1. To obtain Uromune, your doctor first needs to gain SAS(b) approval via the TGA by filling out and submitting the following form (TGA account/login is needed):

<https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/unapproved-products-individual-patients-special-access-scheme#application-pathway-category-b>

In the 'look up records' product drop down box, Uromune is listed as:

“Escherichia Coli/Klebsiella Pneumonia/Enterococcus Faecalis/Proteus Vulgaris (Uromune)”

Approvals usually take between 24-48 hours. Your doctor will receive a “letter of approval/decision” from the TGA by email – we (Inmunotek) will need a copy of this letter.

### Next steps:

2. Prescriber gives the SAS(b) approval letter and Uromune order form to patient or payer (besides patient, the payer could also be a facility such as pharmacy or nursing home).
3. Patient or payer fills in the order form and submits it to us along with the SAS(b) approval letter: [orders@inmunotek.com.au](mailto:orders@inmunotek.com.au)
4. Inmunotek Australia acknowledge receipt of documents and provide the patient/payer with EFT banking details to pay.
5. Once paid, Inmunotek Australia dispatch the Uromune from their Sydney premises to a healthcare facility – they cannot send directly to the patient via a residential address.

### Further information for doctors:

TGA SAS(b) listing = MV140 Uromune

Indication: Prevention of recurrent urinary tract infections (rUTI)

Sponsor name: Immunotek Australia Pty Ltd

Dosage form: Oral spray

Route of administration: Sublingual

Treatment duration: 3 months

Dose & frequency: 2 sprays daily for 3 months

Active ingredient: Inactivated non-lysated Escherichia Coli/Klebsiella  
Pneumonia/Enterococcus Faecalis/Proteus Vulgaris

Strength: 1,000 x 10<sup>6</sup> bacteria/ml