

UROMUNE® is a glycerinated suspension containing whole cell-inactivated bacteria, for sublingual administration.

Composition: the active substances are four whole cell-inactivated bacterial strains: *Klebsiella pneumoniae* (25%), *Escherichia coli* (25%), *Enterococcus faecalis* (25%) and *Proteus vulgaris* (25%) at a final concentration of 300 FTU/mL equivalent to $\sim 10^9$ Bacteria/mL.

Excipients: glycerol, sodium chloride, artificial pineapple flavouring and water for injection.

Pharmaceutical form: sublingual spray, suspension.

Presentations: 1 vial of 6 mL or 2 vials each of 9 mL adequate for approximately 1- or 3-month treatment, respectively. It is packed in an amber glass vial, closed with a plastic cap containing a spray pump and an applicator for spraying, and secured by a seal.

Therapeutic indications: **UROMUNE®** is indicated for adults and paediatric patients for the prevention of recurrent urinary infections of diverse aetiology. It works stimulating the immune system, thereby increasing its resistance against urinary tract infections.

Method of administration: **UROMUNE®** is administered by spraying over the sublingual area. **UROMUNE®** is intended to be administered by the patient himself at home. The proper use of the vial is as follows: remove the plastic seal from the vial to be used. At the beginning of each vial, turn the pipette horizontally and pump the spray 3 or 4 times to ensure the correct filling of the dispenser. Direct the pipette under the tongue, spraying on the sublingual area. Spray twice. Keep the dose under the tongue for approximately 1-2 minutes, and then swallow it. Once the administration is finished, rotate the pipette back to its original vertical downward position, thereby blocking the action of the pump. Place the vial back into the original box.

UROMUNE® administration must be as separated as possible from the intake of meals and/or beverages in order to allow maximum exposure and contact of the product with the administration area. Do not brush teeth or rinse the mouth within 30 minutes of the administration of **UROMUNE®**.

Storage: store in a refrigerator (2-8°C). Keep out of the sight and reach of children.

Date of preparation: March 2020.

*FTU: Formazin Turbidity Unit