

**Prescribing Information:** Otomize 5ml metered dose ear spray delivering 60mg per actuation. **Active ingredients:** Neomycin sulphate 0.5%w/w, dexamethasone 0.1% w/w and glacial acetic acid 2.0% w/w. **Indication:** Treatment of otitis externa. **Dosage:** Spray one metered dose directly into each affected ear three times daily to be continued until two days after the symptoms have disappeared. **Contraindications:** Not suitable for infants and neonates. Where a perforated tympanic membrane is diagnosed or suspected or where a tympanostomy tube (grommet) is in situ. Hypersensitivity to any of the active ingredients or excipients. **Warning and precautions for use:** Discontinue if irritation or rash develops or if the condition worsens or

does not improve within 7 days. Ensure chronic alternative diagnoses are excluded such as otitis media. Prolonged use of corticosteroid/antibiotic combinations may lead to occult extension of infections due to the masking effect of the steroid. Prolonged use may also lead to skin sensitisation, emergence of resistant organisms and a theoretical risk of adrenal suppression in children. **Pregnancy and lactation:** Not recommended during pregnancy. There are no reports of use during lactation and a risk to breast-fed children can not be excluded. **Undesirable effects:** Possible transient stinging or burning sensation for the first few days of treatment. Skin sensitisation/ hypersensitivity reactions. Prescribers should consult the summary of product

characteristics for a full description of possible side-effects. **MA number:** PL 00108/0332. **MA holder:** Forest Laboratories UK Ltd, Dartford, Kent, DA2 6SL, UK. **Legal category:** POM **Basic NHS price:** £3.27 **Further prescribing information can be obtained from:** Forest Laboratories UK Ltd, Riverbridge House, Anchor Boulevard, Crossways Business Park, Dartford, Kent, DA2 6SL, UK. Tel: +44 (0) 1322 421800 **Date created:** August 2014

Information about adverse event reporting can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) Adverse events should also be reported to Forest Laboratories UK Ltd. - Tel: +44 (0) 1322 421800