

Prescribing Information: Otigo (phenazone/lidocaine hydrochloride)

Presentation: Otigo (phenazone/lidocaine hydrochloride) 40 mg/10 mg/g ear drops, solution

Consult the Summary of Product Characteristics (SPC) before prescribing.

Indications: This medicinal product is intended for local symptomatic treatment and relief of pain in the following diseases of the middle ear without tympanic perforation: acute, congestive otitis media; otitis in influenza, the so called viral bullous otitis; barotraumatic otitis. **Dosage and administration:** Bottle with a dropper applicator. Instil 4 drops two or three times daily into the external auditory canal of the affected ear, slightly pressing the elastic part of the dropper. Taking into account that Otigo acts locally, dosage adjustments based on age are not necessary. Otigo is suitable for use both in adults and children. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. Infectious or traumatic perforation of the tympanic membrane (including myringotomy). **Special warnings and precautions for use:** Before the beginning of treatment with the medicinal product, it is recommended to check if there is perforation of the tympanic membrane. If the tympanic membrane is perforated, intra-auricular administration may lead to contact of the product with middle ear structures and cause undesirable effects in these tissues. The product should not be used in the presence of a perforated tympanic membrane, which would include the presence of a myringotomy, in case of penetration of the active substances into the middle ear, risking ototoxicity. The patient should be advised that treatment should be stopped, and medical advice sought, if ear discharge develops during the course of treatment, which may indicate perforation. If symptoms do not improve within 7 days or worsen rapidly or significantly at any time, the therapy should be re-evaluated. Methemoglobinemia has been reported following the topical use of local anaesthetics. Caution should be exercised in patients who are susceptible to methemoglobinemia, including infants under 3 months of age and patients with haemoglobinopathies or Glucose-6-phosphate dehydrogenase (G6PD) deficiency. This medicinal product contains an active substance that can be a reason for positive results of anti-doping tests.

Drug interactions: No interaction studies have been performed. **Fertility, pregnancy and lactation:** In case of intact tympanic membrane, systemic absorption is unlikely. If the recommended dosage (4 drops two or three times daily) and therapy duration (should not exceed 7 days) are observed, the product can be administered during pregnancy and breast-feeding, if necessary. However, women during pregnancy or during breast-feeding should consult their doctor or pharmacist before using Otigo. There is limited pharmacokinetic information available. It is not known if Otigo active substances pass into breast milk or/and cross the placenta. **Undesirable effects:** Rare ($\geq 1/10,000$ to $< 1/1,000$): local allergic reactions (itching, maculopapular rash), auditory canal hyperaemia. **Shelf life:** 3 years. Shelf life after first opening of the bottle – 6 months.

UK Price: 15ml bottle £8.92 **Marketing Authorisation Holder** Renascence Pharma Ltd, The Urban Building Second Floor, 3-9 Albert Street, Slough Berkshire SL1 2BE UK. For further information please contact Lupin Healthcare (UK) Ltd. Tel: 01565 751378. E-mail: information@lupin.com **MA Number:** PL44696/0009

Legal category: POM **Date of revision of the PI:** 24th June 2025

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App store. Adverse events should also be reported to Lupin Healthcare UK Limited

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