PLEASE REFER TO THE SUMMARY OF PRODUCT CHARACTERISTICS FOR FULL PRODUCT INFORMATION.

Presentation: Otigo 40 mg/10 mg/g ear drops, solution

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: 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.

Contradictions: 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 passes into breast milk or/and crosses the placenta.

Undesirable effects:

The undesirable effects listed below are classified according to the affected system or organ and to their frequency. Depending on their frequency, the undesirable effects can be very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data).

Ear and labyrinth disorders: Rare: local allergic reactions (itching, maculopapular rash), auditory canal hyperaemia.

Reporting of suspected adverse reactions: Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

Shelf life: 3 years. Shelf life after first opening of the bottle – 6 months.

Marketing Authorisation Holder:

Renascience Pharma Ltd, Luton Bedfordshire LU1 2BJ

MA Number: PL44696/0009

Legal category: POM

Date of revision of the API text: May 2021

* References available on request

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Renascience Pharma Medical Information: 01582 227 470 or email: medical@renasciencepharma.com