MANUFACTURER	Renascience Pharma Limited
PRODUCT	Otigo Ear Drop Solution Leaflet
PL NUMBER	**44696/0009**
A/W VERSION	Fifth draft
DIMENSIONS	160 x 260 mm
INKS USED	See Below
DATE	05.12.24

TEXT SIZES
Main Body Text 9 pt
Line Spacing as required

Black

Keyline

FONTS USED
Frutiger - Black, Roman & Italic

Bar prints 100mm @ 100%

Package Leaflet: information for the patient
Otigo 40 mg/10 mg/g ear drops, solution
Phenazone/Lidocaine hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Otigo is and what it is used for

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 inflammation of the middle ear;
- middle ear inflammation as a complication after flu;
- barotraumatic damage of the middle ear (so-called barotraumatic otitis).

If in doubt, it is essential to seek the advice of your doctor or your pharmacist.

2. What you need to know before you use Otigo

Do not use Otigo
- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6).
- if you have perforated or burst ear drum (tympanic perforation) this includes cases when your ear drum has been perforated during a surgical manipulation (myringotomy) (see Section: Warnings and precautions).

Warnings and precautions

Talk to your doctor or pharmacist before using Otigo.

If you have perforated ear drum membrane (even when the ear drum membrane was perforated during surgical manipulation) this medicine may cause side effects in the middle ear. Except ear pain, other common symptoms of perforated ear drum are: vertigo (spinning sensation); hearing change or loss, often with ringing, buzzing, or clicking; fluid or blood draining from the ear. It is recommended that the doctor checks if your tympanic membrane (ear drum) is intact, before prescribing this medicine.

Stop using this product and **tell** your doctor if ear discharge develops during the course of treatment.

If symptoms do not improve within 7 days or worsen rapidly or significantly at any time, consult your doctor, who may decide to change your treatment.

The attention of athletes should be drawn to the fact that this medicine contains an active ingredient which may give a positive result in anti-doping tests.

Otigo contains lidocaine (a local anaesthetic) used for pain relief as an active ingredient. Methemoglobinemia (a blood disorder characterized by elevated levels of methemoglobin in the blood, which leads to tissue hypoxia) has been reported following the topical use of local anaesthetics. Otigo should be used with caution 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.

If in doubt, do not hesitate to seek the advice of your doctor or your pharmacist.

Otigo ear drops is a medicinal product intended only for local use in the ear.

It should not be used in the eyes or nose and should not be swallowed.

Other medicines and Otigo
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Driving and using machines
Otigo does not affect the ability to drive and use machines.

Pregnancy, breast-feeding and fertility
Ask your doctor or pharmacist for advice before using any medicine.
Otigo can be used by pregnant and breast-feeding women, if necessary.

3. How to use Otigo

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

To avoid the unpleasant contact of the ear with the cold solution, warm the vial before use between your hands.

Dosage:
Otigo is suitable for use both in adults and children.
The recommended dose is 4 drops, 2 or 3 times daily into the outer ear canal of the affected ear.
If symptoms do not improve within 7 days or worsen rapidly or significantly at any time, the therapy should be re-evaluated, so consult a doctor.

Instructions for use
- Unscrew the bottle cap.
- Screw the dropper applicator.
- Remove the protective dropper cap.
- Tilt your head on one side with your affected ear facing upwards.
- Turn the bottle down and gently squeeze the dropper until a drop is dispensed into the ear.
- Press again to dispense the required number of drops.
- Lie flat on your side.
- Place back the white protective dropper cap after use.

Otigo ear drops is a medicinal product intended only for local use in the ear.
It should not be used in the eyes or nose and should not be swallowed.

If you use more Otigo than you should
There are no reports of overdose cases, when Otigo is properly used.

If you forget to use Otigo
Do not use a double dose to make up for a missed one.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.
The following frequencies are used in evaluating side effects:

Rare side effects (may affect up to 1 in 1,000 people):
local allergic reactions (itching, maculopapular rash), auditory canal hyperaemia.

Reporting side effects
If you get any side effects, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via at: www.mhra.gov.uk/yellowcard or search MHRA Yellow Card in the Google Play or Apple App. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Otigo

Keep this medicine out of the sight and reach of children.
Store in the original package, in order to protect from light.
This medicinal product does not require any special temperature storage conditions.
You can use Otigo 6 months after first opening of the bottle.

Do not use this medicine after the expiry date which is stated on the label and the carton after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacists how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Otigo contains
- The active substances are: phenazone and lidocaine hydrochloride.
- The other ingredients are: sodium thiosulfate, ethanol, glycerol and water.

What Otigo looks like and contents of the pack
Clear, colourless to yellow-brown solution.
15 ml (16.65 g) of the solution are dosed in brown glass (Type III) bottles with capacity of 15 ml. Bottles are closed with polyethylene screw caps with tamper evident rings and sealing inserts.
To dose the medicinal product use a dropper applicator (polypropylene (PP) screw capsule/ thermoplastic elastomer (TPE) reservoir/ low density polyethylene (LDPE) cap) which should be fixed on the bottle after the first opening of the container.

One bottle with a dropper applicator and a package leaflet in a cardboard carton.

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This leaflet was last revised in: December 2024