SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Otomize Ear Spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Neomycin Sulfate	0.5% w/w (3250 IU/ml)
Dexamethasone	0.1% w/w
Glacial Acetic Acid	2.0% w/w

Excipient(s) with known effect
Includes methyl hydroxybenzoate, propyl hydroxybenzoate and stearyl alcohol (see section 4.4).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A milky oil-in-water emulsion as a liquid ear spray for application into the external auditory meatus.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of otitis externa.

4.2 Posology and method of administration

Posology

Adults (including the elderly) and children 2 years of age and over:

Discontinue treatment if there is no clinical improvement after 7 days (see section 4.4).

One metered dose (60mg) to be administered directly into each affected ear three times daily.

Treatment should be continued until two days after symptoms have disappeared.

Infants and neonates (under 2 years of age):

Otomize ear spray is not suitable for infants and neonates (see section 4.3).

Method of administration

Shake the bottle well before use. Before first use, press actuator down several times to obtain a fine spray. Each press then delivers one metered dose. Do not inhale the spray.

Administer spray directly by gently placing nozzle tip into ear opening and pressing down once on the actuator. Use within one month of first use. If there is a period of more than one week since last use, press actuator down a few times before using again.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

The product should not be used in patients where a perforated tympanic membrane has been diagnosed or is suspected or where a tympanostomy tube (grommet) is in situ.

The product should not be used in infants and neonates under 2 years of age.

4.4 Special warnings and precautions for use

Product use should be discontinued, and medical advice sought where appropriate, if irritation or rash occurs, or if the condition worsens or does not improve within 7 days.

When otitis externa is treated topically with preparations containing aminoglycosides, in patients who have a perforation of the tympanic membrane, there is an increased risk of drug induced deafness. It is therefore important to ensure that there is no perforation in such patients (see section 4.3).

It is important to exclude chronic alternate diagnoses, including chronic otitis media, before treatment is commenced.

Treatment with corticosteroid/antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement, since prolonged use may lead to occult extension of infections due to the masking effect of the steroid.

In children there is a theoretical risk that sufficient steroid may be absorbed to cause adrenal suppression, with prolonged use increasing this risk of adrenal suppression in children.

Prolonged use may also lead to skin sensitisation and the emergence of resistant organisms.

Due to potentially immature renal function in children toxicity may develop, thus caution is warranted when administering neomycin in this age group.

Aminoglycoside antibiotics may cause irreversible, partial or total deafness when given systemically or when applied topically to open wounds or damaged skin. This effect is

dose related and is enhanced by renal or hepatic impairment. This possibility should be considered when high doses or prolonged treatment is given to small children.

There have been observed cases of an increased risk of ototoxicity with aminoglycosides administered to patients with mitochondrial mutations, particularly the m.1555A>G mutation, including cases where the patient's aminoglycoside serum levels were within the recommended range. Some cases were associated with a maternal history of deafness and/or mitochondrial mutation. While no cases were identified with neomycin, based on a shared mechanism of action there is the potential for a similar effect with neomycin. These mitochondrial mutations are rare, and the penetrance of this observed effect is unknown.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids

Contains methyl and propyl hydroxybenzoates (E218 and E216) which may cause allergic reactions (possibly delayed).

Contains stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data on the use of dexamethasone in pregnant women. Studies in animals have shown topical administration of corticosteroids to cause reproductive toxicity.
There is a risk of foetal ototoxicity if aminoglycoside antibiotics preparations are administrated during pregnancy.

Otomize is not recommended during pregnancy.

Lactation

No reports describing the use of neomycin or dexamethasone during human lactation are available and the effects on the nursing infant from exposure to the drug in milk are unknown. Maternal use of topical preparations generally carries less risk than a systemically administered drug.

A risk to the breast-fed child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Otomize therapy, taking into

account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines

Unresolved ear problems could themselves affect driving ability.

4.8 Undesirable effects

Eye disorders
Blurred vision has been reported with corticosteroid use; for dexamethasone, the frequency is not known (see also section 4.4)

Skin and subcutaneous tissue disorders
Some patients may experience a transient stinging or burning sensation for the first few days of treatment.

Skin sensitisation / hypersensitivity reactions (immediate and delayed) leading to irritation, burning, stinging, itching and dermatitis.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdosage by this route is extremely unlikely.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: dexamethasone and antiinfectives, S02CA06

Neomycin sulfate is an established antibiotic with a well characterised broad spectrum of activity. Dexamethasone is a well established topical anti-inflammatory steroid. Acetic acid functions to produce a low pH to assist in the control of bacterial infection.

5.2 Pharmacokinetic properties

Otomize ear spray is applied topically to the external auditory meatus and acts locally.

The spray provides excellent distribution and coverage of the surface.

5.3 Preclinical safety data

No additional data of relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol (2) Stearyl Ether
Macrogol (20) Stearyl Ether
Stearyl Alcohol
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

Shelf life after first opening of the container: use within one month of first use

6.4 Special precautions for storage

Store upright in a carton. Do not store above 25°C. Do not freeze.

6.5 Nature and contents of container

The product is supplied in an amber glass bottle of 5ml capacity fitted with a spray device.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Teva UK Limited,
Ridings Point,
Whistler Drive,
Castleford,
WF10 5HX,
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00289/2257

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05/10/1989 / 25/08/2006

10. DATE OF REVISION OF THE TEXT

31/03/2021