1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otomax Ear Drops Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Gentamicin (as gentamicine sulfate)	2640 IU
Betamethasone (as bethametasone valerate)	0.88 mg
Clotrimazole	8.80 mg

Excipients:

Qualitative composition of excipients and other constituents
Paraffin, liquid
Plasticized Hydrocarbon Gel Ointment Base

Ear drops suspension.
A smooth, uniform, white to off-white viscous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of acute external otitis. Also, for treatment of short term exacerbation of the acute signs of chronic external otitis of bacterial and fungal origin due to bacteria susceptible to gentamicin, such as *Staphylococcus intermedius*, and fungi susceptible to clotrimazole, in particular *Malassezia pachydermatis.*

3.3 Contraindications

Do not administer to dogs with a perforated eardrum.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

Bacterial and fungal otitis is often secondary in nature. The underlying cause should be identified and treated.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Contact with eyes should be avoided. In case of accidental contact, flush with plenty of water.

Before the veterinary medicinal product is applied, the external auditory canal must be examined thoroughly to ensure that the eardrum is not perforated in order to avoid the risk of transmission of the infection to the middle ear and to prevent damage to the cochlear and vestibular apparatus.

The outer ear should be cleaned meticulously and dried before treatment. Excess hair around the treatment area should be cut.

Use of the veterinary medicinal product should be based on susceptibility of isolated bacteria and/or other appropriate diagnostic tests. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to gentamicin and may decrease the effectiveness of treatment with other aminoglycosides, due to the potential for cross resistance.

Prolonged and intensive use of topical corticosteroids preparation is known to trigger local and systemic effects, including suppression of adrenal function, thinning of the epidermis and delayed healing.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid contact with the veterinary medicinal product.
Wash hands carefully after applying the veterinary medicinal product. In case of accidental contact with the eyes, rinse with plenty of water.

People with known hypersensitivity to ingredients should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site erythema[1], application site papule[1]; Impaired hearing[2,3,5], loss of hearing[3,4,5], vestibular disorder[5].

[1] These lesions regress when treatment is discontinued.

[2] Temporary.

[3] Especially in elderly animals.

[4] Can be irreversible in extremely rare cases.

[5] In the event of auditory or vestibular dysfunction, treatment must be discontinued immediately and the auditory canal cleaned carefully using a non-ototoxic solution.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not administer to pregnant or lactating bitches.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer the veterinary medicinal product concurrently with other substances known to cause ototoxicity.

3.9 Administration routes and dosage

Auricular use.

Shake the veterinary medicinal product well before administration.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Dogs weighing less than 15 kg: Apply 4 drops to the ear twice a day.
Dogs weighing more than 15 kg: Apply 8 drops to the ear twice a day.
The duration of treatment is 7 days.

After application the base of the ear may be massaged briefly and gently to allow the preparation to penetrate to the lower part of the ear canal.

1 drop of the veterinary medicinal product corresponds to 66.9 IU gentamicin, 22.3 µg betamethasone and 223 µg clotrimazole.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Local and transient eruptions of papules have been observed at 5 times the recommended dosage.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QS02CA90

4.2 Pharmacodynamics

Gentamicin sulphate is an aminoglycoside bactericidal antibiotic which acts by inhibiting protein synthesis. Its spectrum of activity includes Gram-positive and Gram-negative bacteria, such as the following pathogenic organisms isolated from the ears of dogs: *Staphylococcus intermedius*, coagulase-positive *Staphylococcus* spp. and *Proteus mirabilis*.

Betamethasone valerate is a synthetic dexamethasone-analogue corticosteroid with an anti-inflammatory, anti-pruritic activity when applied topically. It has mild mineralocorticoid properties. Betamethasone valerate is absorbed after topical application. Absorption may be increased if there is inflammation of the skin.

Clotrimazole is an antifungal agent which acts by causing changes in the cell membrane, which lead to a loss of intracellular components and consequently to a cessation of molecular synthesis.
Clotrimazole has a broad spectrum of activity and is used in the treatment of skin conditions caused by various species of pathogenic dermatophytes and by moulds, in particular *Malassezia pachydermatis*.

4.3 Pharmacokinetics

Not documented.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf-life after first opening the immediate packaging: 14 days.

5.3 Special precautions for storage

Do not store above 25 ℃.

5.4 Nature and composition of immediate packaging

Containers and closures:

Bottles:
High density polyethylene (HDPE) bottle with filling volumes of 14 mL or 34 mL with a low density polyethylene (LDPE) cap and LDPE applicator/cap.

Tubes:
8.5 mL and 17 mL lined aluminium tubes with HDPE white screw cap and LDPE applicator/cap.

Package sizes:

Box containing 1 tube of 8.5 mL
Box containing 1 tube of 17 mL
Box containing 1 plastic bottle of 14 mL
Box containing 1 plastic bottle of 34 mL
Box containing 6 tubes of 8.5 mL
Box containing 6 tubes of 17 mL
Box containing 12 tubes of 8.5 mL
Box containing 12 tubes of 17 mL

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/244/001

8. DATE OF FIRST AUTHORISATION

07/09/2012

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

11/12/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).