PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otomax Ear Drops Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains gentamicin sulphate equivalent to 2640 IU gentamicin base, betamethasone valerate equivalent to 0.88 mg betamethasone and 8.80 mg clotrimazole.

3. PACKAGE SIZE

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

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Auricular use.
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 14 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

14. MARKETING AUTHORISATION NUMBER

Vm 01708/4588

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE, TUBE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otomax Ear Drops Suspension

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml containsgentamicin sulphate equivalent to 2640 IU gentamicin base, betamethasone valerate equivalent to 0.88 mg betamethasone and 8.80 mg clotrimazole.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 14 days

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:
PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Otomax Ear Drops Suspension

2. Composition

Each ml contains:

Active substances:

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

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

3. Target species

Dogs.

4. Indications for use

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.*

5. Contraindications

Do not administer to dogs with a perforated eardrum.
Do not administer in the case of hypersensitivity to any of the ingredients.

6. Special warnings

Special precautions for safe use in the target species:
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.

Contact with eyes should be avoided. In case of accidental contact, flush with plenty of water.
Bacterial and fungal otitis is often secondary in nature. The underlying cause should be identified and treated.

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 copious amounts of water.
Do not handle the veterinary medicinal product if you have known hypersensitivity against compounds in the veterinary medicinal product.

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

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.

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

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

7. 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. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

Shake well before use.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the

container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

14. Marketing authorisation number and pack sizes

Vm 01708/4588

The veterinary medicinal product is supplied in high density polyethylene bottles with filling volumes of either 14 or 34 ml with a low density polyethylene (LDPE) cap and LDPE applicator/cap, or as .5 ml and 17 ml lined aluminium tubes with HDPE white screw cap and LDPE applicator/cap. The following pack sizes are available, however not all pack sizes may be marketed.

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ
United Kingdom
Tel.: +44 (0)1908 685685

Manufacturers responsible for batch release:

TriRx Segré
La Grindolière
Zone Artisanale Segré
49500 Segré-en-Anjou Bleu
France

17. Other information

POM-V

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*.

For animal treatment only.

Gavin Hall
Approved: 07 April 2025