SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otomax Ear Drops Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of the veterinary medicinal product contains:
Active substance:

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

Excipient(s):
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the 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.*

4.3 Contraindications

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

See also section 4.7
See also section 4.8

4.4 Special warnings

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.

4.5 Special precautions for use

i. Special precautions for use in animals

Before the 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 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 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.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid contact with the product.
Wash hands carefully after applying the product. In case of accidental contact with the eyes, rinse with copious amounts of water.
Do not handle the product if you have known hypersensitivity against compounds in the product.

4.6 Adverse reactions (frequency and seriousness)

Erythematous papules may appear locally; these lesions regress when treatment is discontinued.

Temporary impairment of hearing and extremely rare cases of irreversible loss of hearing have been observed, especially in elderly animals.
In the event of auditory or vestibular dysfunction, treatment must be discontinued immediately and the auditory canal cleaned carefully using a non-ototoxic solution.

Prolonged and extensive use of topical corticosteroid preparations have been known to induce local and systemic side-effects. These include suppression of adrenal function, epidermal thinning, and delayed wound healing.

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant or lactating bitches.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

For otic use only.

Shake the product well before administration.

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 product corresponds to 66.9 IU gentamicin, 22.3µg betamethasone and 223 µg clotrimazole.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Otologicals corticosteroids and antiinfectives in combination

ATC vet code: QS02CA90

5.1 Pharmacodynamic properties

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*.

5.2 Pharmacokinetic particulars

Not documented.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin Liquid
Plasticized Hydrocarbon Gel Ointment Base

6.2 Incompatibilities

None known.

6.3 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

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 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.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4588

9. DATE OF FIRST AUTHORISATION

22 July 1999

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 14 August 2020