ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otomax Ear Drops Suspension

2. STATEMENT OF ACTIVE AND OTHER 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. PHARMACEUTICAL FORM

Ear drops suspension

4. 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

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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.*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. SPECIAL WARNING(S), IF NECESSARY

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.

9. EXPIRY DATE

EXP {month/year}

10. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

11. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

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

Keep out of the reach and sight of children.

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4588

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otomax Ear Drops Suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

14 mL
34 mL

Keep the container in the outer carton.

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. BATCH NUMBER

Batch {number}

6. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 14 days

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Otomax Ear Drops Suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

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

Manufacturer for the batch release:

Schering-Plough Canada Inc.
3535 Trans-Canada Highway
Pointe-Claire, Québec, H9R 1B4
Canada / Canada

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Otomax Ear Drops Suspension

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

4. INDICATION(S)

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 known hypersensitivity to any of the ingredients.

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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, 22.3 µg betamethasone and 223 µg clotrimazole.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 25 °C.

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

Do not use after the expiry date stated on the bottle or carton.

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 WARNING(S)

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 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.

Do not administer to pregnant or lactating bitches.

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

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

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

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.
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.

Approved: 13/01/21