LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mometamax Ultra ear drops, suspension for dogs
gentamicin, posaconazole, mometasone furoate

2. STATEMENT OF ACTIVE SUBSTANCES

1 dose (0.8 ml): 6880 IU gentamicin, 2.08 mg posaconazole, 1.68 mg mometasone furoate

3. PHARMACEUTICAL FORM

Ear drops, suspension

4. PACKAGE SIZE

20 doses
20 syringes

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Auricular use.
Single treatment.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Once opened use within 3 months.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.
Keep the bottle in the outer carton.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-V To be supplied only on veterinary prescription.

Administration by a veterinarian surgeon or under their close supervision.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/5062

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Multidose bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mometamax Ultra ear drops, suspension for dogs
gentamicin, posaconazole, mometasone furoate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 dose (0.8 ml): 6880 IU gentamicin, 2.08 mg posaconazole, 1.68 mg mometasone furoate.

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

20 doses

4. ROUTE(S) OF ADMINISTRATION

Auricular use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP
Once opened use within 3 months.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Mometamax Ultra ear drops, suspension for dogs

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 Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Vet Pharma Friesoythe GmbH
Sedelsberger Straße 2 - 4
26169 Friesoythe
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mometamax Ultra ear drops, suspension for dogs
gentamicin, posaconazole, mometasone furoate

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

Each dose (0.8 ml) contains:
Gentamicin sulfate equivalent to 6880 IU gentamicin (6.88 mg)
Posaconazole 2.08 mg
Mometasone furoate monohydrate equivalent to 1.68 mg mometasone furoate

Ear drops, suspension.
Smooth, uniform, white to off-white, viscous suspension.

4. INDICATION(S)

Treatment of acute otitis externa and acute exacerbation of recurrent otitis externacaused by mixed infections of susceptible strains of bacteria sensitive to gentamicin (*Staphylococcus pseudintermedius*) and fungi sensitive to posaconazole (*Malassezia pachydermatis*).

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use if the eardrum is perforated.
Do not use in pregnant or breeding animals.
Do not use concurrently with substances known to cause ototoxicity.
Do not use in dogs with generalised demodicosis.

6. ADVERSE REACTIONS

No adverse reactions related to treatment were observed in clinical trials.

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

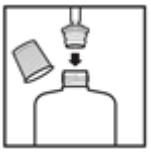
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Auricular use.
Single treatment.
The recommended dosage is a single dose of 0.8 ml per infected ear.
The maximum clinical response may not be seen until 28 days after administration.

9. ADVICE ON CORRECT ADMINISTRATION

Clean and dry the external ear canal before administering the product. The product is preservative-free and should be handled using clean technique.

Before first use, shake the bottle vigorously for 15 seconds. Unwrap the syringe with the adapter attached. Remove the cap from the bottle and insert the syringe adapter by pressing it firmly into the top of the bottle using the attached syringe.



1. Invert the bottle and draw up 0.8 ml per ear.
2. Return the bottle to an upright position and remove the syringe from the adapter.
3. Leave the syringe adapter in place and replace the cap on the bottle.
4. Place the tip of the syringe at the entrance of external ear and administer the 0.8 ml dose. The applied dose will flow into the ear canal.

5. After application, the ear can be massaged gently to ensure distribution of the product throughout the ear canal.
   Following dosing, the head should be restrained for approx. 2 minutes to prevent shaking and dislodging of product.

Use a new syringe for each infected ear. Shake the bottle vigorously for 15 seconds before use. Remove the cap. Insert the syringe tip into the adapter. Follow steps 1. to 5. of the dosing instructions.

Dosing syringes compatible with the syringe adapter are provided. Some commercially available syringes may not be compatible with the syringe adapter.

Do not clean the ear canal for at least 28 days after the administration to allow contact of the product with the ear canal.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Keep the bottle in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the outer carton and bottle after EXP.

Shelf life after first opening the container: 3 months.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Ears must be cleaned before administration of the product. Do not repeat ear cleaning unless clinically indicated until 28 days after administration. Compatibility with ear cleaners, other than saline solution, has not been demonstrated. Antimicrobial activity may be reduced by low pH and the presence of pus and/or debris.

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

Water should not be allowed to enter the external ear canal of treated dogs for 28 days.

Cross-resistance has been shown between gentamicin and antimicrobial(s) in the same related class in the target pathogen. Use of the product should be carefully considered when susceptibility testing has shown resistance to aminoglycosides because its effectiveness may be reduced.

Special precautions for use in animals:
The safety of the product has not been established in dogs less than 3 months of age or weighing less than 2.8 kg.

Before the veterinary medicinal product is applied, the external auditory canal must be examined thoroughly to ensure that the ear drum 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.

This antimicrobial combination should only be used where diagnostic testing has indicated the need for simultaneous administration of each of the active substances.

Use of the veterinary medicinal product deviating from the instructions given in the Summary of Product Characteristics (SPC) may increase the prevalence of bacteria resistant to gentamicin and fungi resistant to posaconazole and may decrease the effectiveness of treatment with other antibiotics and antifungal agents.

Whenever possible the veterinary medicinal product should only be used based on identification of infecting organisms and susceptibility testing.

In case of parasitic otitis, an appropriate acaricidal treatment should be implemented.

In a tolerance study, lower baseline and ACTH-induced cortisol levels were observed at 3X and 5X dose levels. These findings are consistent with adrenocortical suppression associated with glucocorticoid administration. At the end of the study, ACTH-stimulation elicited an increase in cortisol levels indicative of sufficient adrenal function.

Prolonged and intensive use of topical corticosteroid preparations is known to trigger systemic effects, including suppression of adrenal function.

Use with caution in dogs with a suspected or confirmed endocrine disorder (i.e. diabetes mellitus; hypothyroid disease, etc.).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product may be slightly irritating to eyes. Accidental eye exposure may occur when the dog shakes its head during or just after administration. In case of accidental eye contact, flush the eyes thoroughly with water for 15 minutes. If symptoms develop, seek medical advice and show the package leaflet or the label to a physician.

Although no potential for skin irritation was indicated by experimental studies, contact of the product with the skin should be avoided. In case of accidental skin contact, wash the exposed skin with water.

Close contact between the dog and children should be limited in the days following the treatment due to unknown amount of the product possibly leaking from treated ear/s.

The product may be harmful after ingestion. Avoid ingestion of the product including hand-to-mouth exposure. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use during pregnancy and lactation.

Fertility:
Studies to determine the effect on fertility in dogs have not been conducted. Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:
None known.

In clinical trials, only saline was used for ear cleaning before treatment initiation with the veterinary medicinal product. Compatibility with ear cleaners, other than saline solution, has not been demonstrated.

Overdose (symptoms, emergency procedures, antidotes):
Auricular administration to puppies at up to 5 times the recommended dose to both ears on 3 occasions at 2-week intervals was evaluated in a target animals safety study.

All findings were consistent with glucocorticoid administration. Findings in the 3X and 5X overdose groups included mild eosinopenia, lower baseline and ACTH-induced cortisol levels, lower mean adrenal weights with correlating minimal to mild atrophy of the adrenal cortex. A minimal to mild atrophy of the epidermis of the external auditory canal and the epithelium lining of the external surface of the tympanic membrane was observable in the 1X, 3X and 5X groups, consistent with the pharmacological effects of glucocorticoids and known to be reversible after cessation of treatment. ACTH administration at the end of the study elicited an increase in cortisol levels in all study groups, indicative of sufficient adrenal function.

All findings were of low severity, are considered reversible after cessation of treatment, and were not associated with clinical signs or hearing effects.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2023

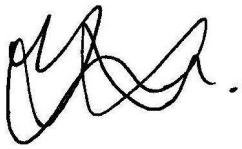
15. OTHER INFORMATION

For animal treatment only.

Pack size:
Carton box containing 1 bottle, an LDPE adaptor and 20 syringes.

POM-V To be supplied only on veterinary prescription.

Vm 01708/5062



Approved: 17 February 2023