ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mometamax Ultra ear drops, suspension for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.8 ml) contains:

Active substances:

Gentamicin sulfate equivalent to	6880 IU gentamicin
Posaconazole	2.08 mg
Mometasone furoate monohydrate equivalent to	1.68 mg mometasone furoate

Excipients:

Qualitative composition of excipients and other constituents
Paraffin liquid
Plasticized hydrocarbon gel (polyethylene, mineral oil)

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 otitis externa or acute exacerbation of recurrent otitis externa caused by mixed bacterial and fungal infections with *Staphylococcus pseudintermedius* and *Malassezia pachydermatis*.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients, to corticosteroids, to other azole antifungal agents and to other aminoglycosides.
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.

3.4 Special warnings

Antimicrobial activity can be reduced by low pH and the presence of purulent and/or inflammatory debris. Ears must be cleaned before administration of the veterinary medicinal product. Compatibility with ear cleaners has not been demonstrated.

Bacterial and fungal otitis is often secondary to other conditions. In animals with a history of recurrent otitis externa, the underlying causes of the condition such as allergy or anatomical conformation of the ear must be addressed in order to avoid ineffective treatment with this veterinary medicinal product.

Efficacy of this veterinary medicinal product was not assessed in dogs with atopic or allergic skin conditions.

Cross-resistance between gentamicin and other members of the aminoglycoside class has been shown in *Staphylococcus pseudintermedius*. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to aminoglycosides because its effectiveness may be reduced. Co-selection for resistance to other classes of antimicrobials is common (see section 4.2).

3.5 Special precautions for use

Special precautions for safe use in the target species:
The safety of the veterinary medicinal product has not been established in dogs less than 3 months of age or weighing less than 3 kg.

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.

Re-evaluate the dog immediately if worsening of clinical signs, hearing loss or signs of vestibular dysfunction are observed during treatment or if the dog is not showing signs of improvement by day 14.

Cytology of ear canal is recommended prior to the use of the veterinary medicinal product to identify a mixed infection.

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 should be based on identification and susceptibility testing of the target pathogens. Ideally, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted.

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

Prolonged and intensive use of topical corticosteroids preparation is known to trigger systemic effects, including suppression of adrenal function (see section 3.10).

Use with precaution in dogs with suspected or confirmed endocrine disorder (i.e. diabetes mellitus; hypo-thyroid disease, etc).

Ototoxicity may be associated with gentamicin treatment. Experience shows that geriatric dogs are more at risk of hearing impairment after topical ear product administration.

Objective hearing assessments were not performed in the pivotal field trial. Dogs with signs of impaired balance or loss of hearing after administration should be re-examined.

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 veterinary medicinal 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 veterinary medicinal product possibly leaking from treated ear/s.

The veterinary medicinal product may be harmful after ingestion. Avoid ingestion of the veterinary medicinal 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.

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

3.6 Adverse events

Dogs:
No adverse events related to treatment were observed in clinical trials.

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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 to 42 days after administration.

Instructions for use:
The veterinary medicinal product should be administered only by veterinarians or by trained personnel under close veterinary supervision.

Clean and dry the external ear canal before administering the veterinary medicinal product.

The veterinary medicinal 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 adapter by pressing it firmly into the top of the bottle using the attached syringe. Follow steps 1. to 5. of the dosing instructions.

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 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 veterinary medicinal product throughout the ear canal. Following dosing, the head should be restrained for approx. 2 minutes to prevent shaking and dislodging of veterinary medicinal product.

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

It is recommended not to repeat ear cleaning for at least 28 days after administration unless clinically indicated. Care should also be taken to avoid water entering the ear canal during this period. For this reason, dogs should not be bathed nor allowed to swim until confirmation of clinical cure 28-42 days after treatment.

Dogs should be re-examined 28-42 days after veterinary medicinal product administration to assess response to treatment. After confirmation of clinical resolution, the ears should be cleaned to remove any remaining debris or residual veterinary medicinal product.

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

Auricular administration to puppies at up to 5 times the recommended dose to both ears on 3 occasions at 2-week intervals was well-tolerated.

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. Minimal to mild atrophy of the epidermis of the external auditory canal and the epithelium of the external surface of the tympanic membrane, consistent with the pharmacological effects of glucocorticoids, was observable in the 1X, 3X and 5X group, and shown 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 and are considered reversible after cessation of treatment.

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

For administration only by a veterinarian.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QS02CA91.

4.2 Pharmacodynamics

The veterinary medicinal product is a fixed combination of three active substances (antibiotic, antifungal and corticosteroid).

Gentamicin is an aminoglycoside bactericidal, concentration-dependent antibiotic. Its mechanism of action involves inhibition of bacterial protein synthesis by binding to 30S ribosomes. In *S. pseudintermedius*, the most common mechanism of antimicrobial resistance is the production of aminoglycoside modifying enzymes encoded by the transposon-borne resistance genes, aac(6')-aph(2''), conferring cross-resistance to all aminoglycosides with the exception of streptomycin. In addition, co-resistance selection of resistance against other classes of antibiotics is commonly seen (including tetracyclines, oxacillin (MRSP), macrolides etc) in various bacterial species including *S. pseudintermedius* (e.g. MRSP).

Posaconazole is a broad-spectrum triazole antifungal agent. The mechanism by which posaconazole exerts fungicidal action involves the selective inhibition of the enzyme lanosterol 14-demethylase (CYP51) involved in ergosterol biosynthesis in yeasts and filamentous fungi. In *in vitro* tests, posaconazole has shown fungicidal activity against most of the approximately 7,000 strains of yeast and filamentous fungi tested. Posaconazole is 40 – 100 times more potent *in vitro* against *Malassezia pachydermatis* than clotrimazole, miconazole, nystatin and terbinafine.

The most common mechanisms of resistance to azoles in clinical isolates are alterations in lanosterol 14α-demethylase biosynthesis (e.g. by mutations), increased production of this enzyme or increased efflux (e.g. by ABC transporters or major facilitators). Posaconazole is not an MDR1 major facilitator substrate.

Mometasone furoate is a corticosteroid with high topical potency, but few systemic effects. Like other topical corticosteroids, it has anti-inflammatory and anti-pruritic properties.

Table 1: Minimum Inhibitory Concentration (MIC) range, MIC_{50} and MIC_{90} of gentamicin determined for *Staphylococcus pseudintermedius* isolates (n=50).

Species	**MIC range mcg/ml**	**MIC_{50} mcg/ml**	**MIC_{90} mcg/ml**
Staphylococcus pseudintermedius	≤ 0.063 - 16	0.125	0.25

Table 2: MIC range, MIC_{50} and MIC_{90} of posaconazole determined for *Malassezia pachydermatis* isolates (n=50).

Species	**MIC range mcg/ml**	**MIC_{50} mcg/ml**	**MIC_{90} mcg/ml**
Malassezia pachydermatis	≤ 0.016	≤ 0.016	≤ 0.016

All isolates were collected from dogs between 2017 and 2020 in different European countries and were epidemiologically unrelated.

4.3 Pharmacokinetics

Systemic absorption and depletion from the ear wax of the three active substances was determined after a single administration of the recommended dose into both ear canals of healthy beagle dogs. Plasma and ear wax concentrations were measured at 1, 7, 14, 21, 30, and 45 days post-administration.

Systemic exposure was only detected at 1-day post-administration with low plasma concentrations (≤ 7.9 ng/ml) of gentamicin and posaconazole. At 14 days and 45 days post-administration, only one dog out of eight was found to have a detectable amount of gentamicin and posaconazole in the plasma, respectively. Plasma concentrations for all other time points for gentamicin and posaconazole were below the limit of quantification. Plasma concentrations of mometasone furoate were below the limit of quantification at every time point.

Gentamicin, posaconazole, and mometasone furoate were detected in ear wax throughout the 45 day study with depletion occurring progressively. From days 1 to 14, concentrations of all three active substances were detectable in all animals. The number of animals with concentrations of active ingredients below the limit of quantification gradually increased (depending on the active ingredient) from one or two animals on day 21 to most of the animals on day 45 days post-administration. Gentamicin concentrations were above ten times the MIC90 of *S. pseudintermedius* in the majority of samples for 30 days post treatment.

The extent of transcutaneous absorption of topical medications is determined by many factors including the integrity of the epidermal barrier. The influence on the absorption of the veterinary medicinal product by factors such as inflammation and skin atrophy associated with prolonged treatment with glucocorticoids has not been established.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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: 3 months.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

White high-density polyethylene (HDPE) bottle with a white low-density polyethylene (LDPE) screw cap. One bottle contains sufficient veterinary medicinal product to withdraw 20 doses of 0.8 ml.

Polypropylene syringes of 1.0 ml capacity
Carton box containing 1 bottle, an LDPE adapter and 20 syringes.

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 International B. V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/22/289/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 22 November 2022

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

{DD/MM/YYYY}

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*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

20 doses
20 syringes

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Auricular use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

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

Intervet International BV

14. MARKETING AUTHORISATION NUMBERS

EU/2/22/289/001

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

MULTIDOSE BOTTLE / HDPE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mometamax Ultra

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 3 months.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Mometamax Ultra ear drops, suspension for dogs

2. Composition

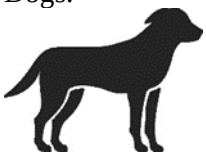
Each dose (0.8 ml) contains:

Gentamicin sulfate equivalent to	6880 IU gentamicin
Posaconazole	2.08 mg
Mometasone furoate monohydrate equivalent to	1.68 mg mometasone furoate

White to off-white, viscous suspension.

3. Target species

Dogs.



4. Indications for use

Treatment of acute otitis externa or acute exacerbation of recurrent otitis externa caused by mixed bacterial and fungal infections with *Staphylococcus pseudintermedius* and *Malassezia pachydermatis*.

5. Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients, to corticosteroids, to other azole antifungal agents and to other aminoglycosides.
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. Special warnings

Special warnings:
Antimicrobial activity can be reduced by low pH and the presence of purulent and/or inflammatory debris. Ears must be cleaned before administration of the veterinary medicinal product. Compatibility with ear cleaners has not been demonstrated.

Bacterial and fungal otitis is often secondary to other conditions. In animals with a history of recurrent otitis externa, the underlying causes of the condition such as allergy or anatomical conformation of the ear must be addressed in order to avoid ineffective treatment with this veterinary medicinal product. Efficacy of this veterinary medicinal product was not assessed in dogs with atopic or allergic skin conditions.

Cross-resistance between gentamicin and other members of the aminoglycoside class has been shown in *Staphylococcus pseudintermedius*. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to aminoglycosides because its effectiveness may be reduced. Co-selection for resistance to other classes of antimicrobials is common.

Special precautions for safe use in the target species:
The safety of the veterinary medicinal product has not been established in dogs less than 3 months of age or weighing less than 3 kg.

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.

Re-evaluate the dog immediately if worsening of clinical signs, hearing loss or signs of vestibular dysfunction are observed during treatment or if the dog is not showing signs of improvement by day 14.

Cytology of ear canal is recommended prior to the use of the veterinary medicinal product to identify a mixed infection.

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 should be based on identification and susceptibility testing of the target pathogens. Ideally, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted.

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

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

Use with precaution in dogs with suspected or confirmed endocrine disorder (i.e. diabetes mellitus; hypo-thyroid disease, etc).

Ototoxicity may be associated with gentamicin treatment. Experience shows that geriatric dogs are more at risk of hearing impairment after topical ear veterinary medicinal product administration.

Objective hearing assessments were not performed in the pivotal field trial. Dogs with signs of impaired balance or loss of hearing after administration should be re-examined.

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 veterinary medicinal 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 veterinary medicinal product possibly leaking from treated ear/s.

The veterinary medicinal product may be harmful after ingestion. Avoid ingestion of the veterinary medicinal 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.

Overdose:
Auricular administration to puppies at up to 5 times the recommended dose to both ears on 3 occasions at 2-week intervals was well-tolerated.

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. Minimal to mild atrophy of the epidermis of the external auditory canal and the epithelium of the external surface of the tympanic membrane, consistent with the pharmacological effects of glucocorticoids, was observable in the 1X, 3X and 5X group, and shown 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 and are considered reversible after cessation of treatment.

7. Adverse events

Dogs:

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

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: {national system details}.

8. Dosage for each species, routes 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 to 42 days after administration.

9. Advice on correct administration

The veterinary medicinal product should be administered only by veterinarians or by trained personnel under close veterinary supervision.

Clean and dry the external ear canal before administering the veterinary medicinal product.

The veterinary medicinal 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 adapter by pressing it firmly into the top of the bottle using the attached syringe. Follow steps 1. to 5. of the dosing instructions.

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 veterinary medicinal product throughout the ear canal. Following dosing, the head should be restrained for approx. 2 minutes to prevent shaking and dislodging of veterinary medicinal product.

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

It is recommended not to repeat ear cleaning for at least 28 days after administration unless clinically indicated. Care should also be taken to avoid water entering the ear canal during this period. For this reason, dogs should not be bathed nor allowed to swim until confirmation of clinical cure 28-42 days after treatment.

Dogs should be re-examined 28-42 days after veterinary medicinal product administration to assess response to treatment. After confirmation of clinical resolution, the ears should be cleaned to remove any remaining debris or residual veterinary medicinal product.

10. Withdrawal periods

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton box and bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months.

12. Special precautions for disposal

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 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

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/22/289/001
Carton box containing 1 bottle, an LDPE adapter and 20 syringes.

15. Date on which the package leaflet was last revised

{DD month YYYY}

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: + 420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

España
Tel: + 34 923 19 03 45

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Κύπρος
Τηλ: + 30 210 989 7452

Latvija
Tel: + 37052196111

Polska
Tel.: + 48 22 18 32 200

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Slovenská republika
Tel: + 420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220

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