ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Easotic ear drops, suspension for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Hydrocortisone aceponate	1.11 mg/ml
Miconazole as nitrate	15.1 mg/ml
Gentamicin as sulphate	1,505 IU/ml.

Excipient:

Qualitative composition of excipients and other constituents
Liquid paraffin.

A white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of acute otitis externa, and acute exacerbation of recurrent otitis externa associated with bacteria susceptible to gentamicin and fungi susceptible to miconazole in particular *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 concurrently with substances known to cause ototoxicity.
Do not use in dogs with generalised demodicosis.

3.4 Special warnings

Bacterial and fungal otitis is often secondary in nature and appropriate diagnosis should be used to determine the primary factors involved.

3.5 Special precautions for use

Special precautions for safe use in the target species:

If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted.
Use of the veterinary medicinal product should be based on identification of infecting organisms and susceptibility testing and take into account official and local antimicrobial policies.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria and fungi resistant to gentamicin and miconazole respectively and may

decrease the effectiveness of treatment with aminoglycosides and azole antifungal agents, due to the potential for cross-resistance.
In case of parasitic otitis, an appropriate acaricidal treatment should be implemented.
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.
Gentamicin is known to be associated with ototoxicity when administered by the systemic route at higher doses.

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

In case of accidental skin contact, it is recommended to wash thoroughly with water.
Avoid contact with eyes. In case of accidental contact, rinse with abundant quantities of water. In case of eye irritation, seek medical advice.
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:

Common (1 to 10 animals / 100 animals treated):	Application site reddening (ear) [1,2]
Uncommon (1 to 10 animals / 1,000 animals treated):	Application site papule [2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Impaired Hearing [3,4], Deafness [3,4] Hypersensitivity reactions (facial swelling, allergic pruritus) [4]

[1] Mild to moderate.
[2] Recovering without specific therapy.
[3] Primarily in geriatric dogs.
Complete recovery was confirmed in 70% of post marketing cases with an adequate follow-up, otherwise hearing improvement was observed in most dogs.
Recovery has been observed between one week and up to two months after onset of signs.
[4] If the adverse reaction occurs, treatment should be stopped.

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 its local representative 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.
Systemic absorption of hydrocortisone aceponate, gentamicin sulphate and miconazole nitrate being negligible, it is unlikely for teratogenic, foetotoxic or maternotoxic effects to occur at the recommended dosage in dogs.
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

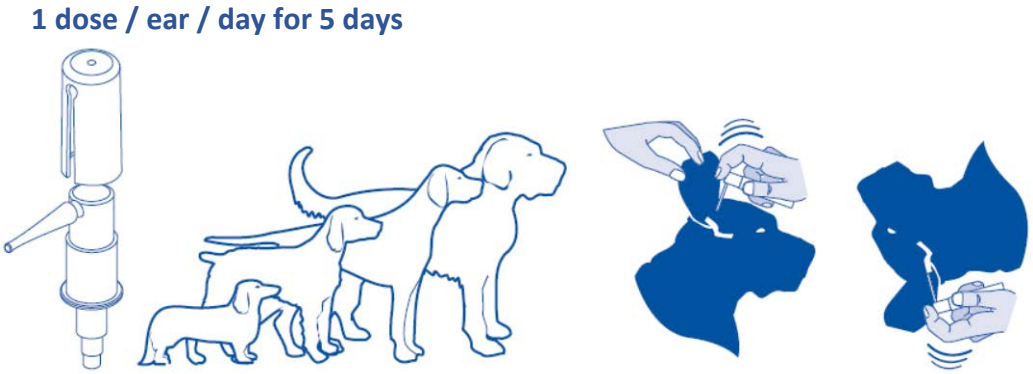
3.8 Interaction with other medicinal products and other forms of interaction

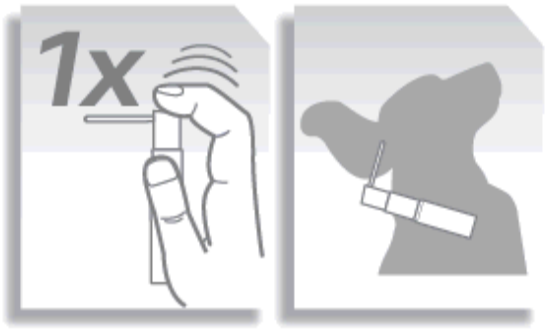
Compatibility with ear cleaners has not been demonstrated.

3.9 Administration routes and dosage

Auricular use.
One ml contains 1.11 mg hydrocortisone aceponate, 15.1 mg miconazole (as nitrate) and 1,505 IU gentamicin (as sulphate).
It is recommended that the external ear canal should be cleaned and dried before treatment and excess hair around the treatment area be cut.
The recommended dosage is 1 ml of the veterinary medicinal product per infected ear once a day for five consecutive days.

Multi-dose container:
Shake the bottle thoroughly before first administration and prime the pump by pressing it.
Introduce the atraumatic canula in the ear canal. Administer one dose (1 ml) of the product in each affected ear. This dose is adequately delivered by one pump activation. The airless pump allows the product to be administered whatever the position of the bottle is.





The product as presented allows treating a dog suffering from bilateral otitis.

Single-dose container:
To administer one dose (1 ml) of the product in the affected ear:

- Take out one pipette from the box.
- Shake the pipette thoroughly before use.
- To open: hold up the pipette upright and break the top of the cannula.
- Introduce the atraumatic cannula in the ear canal. Squeeze gently but firmly in the middle of the body of the pipette.

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.

The veterinary medicinal product should be used at room temperature (i.e. do not instil cold product).

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

At 3 and 5 times the recommended dose, no local or general adverse reactions were observed with the exception of some dogs showing erythema and papulae in the ear canal.
In dogs treated at the therapeutic dose for ten consecutive days, serum cortisol levels decreased from five days onward and returned to normal values within ten days after the end of treatment. However, serum cortisol response levels post ACTH stimulation remained in the normal range during the extended treatment period, indicating a preserved adrenal function.

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QS02CA03

4.2 Pharmacodynamics

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

Hydrocortisone aceponate belongs to the diester class of the glucocorticosteroids with a potent intrinsic glucocorticoid activity which means a relief of both inflammation and pruritus leading to an improvement of clinical signs observed in otitis externa.

Miconazole nitrate is a synthetic imidazole derivative with a pronounced antifungal activity. Miconazole selectively inhibits the synthesis of ergosterol, which is an essential component of the membrane of yeasts and fungi including *Malassezia pachydermatis*. Mechanisms of resistance to azoles consist of either failure in antifungal accumulation or modification of target enzyme. No standardised *in-vitro* susceptibility breakpoints have been defined for miconazole; however, using the method by Diagnostics Pasteur, no resistant strains were found.

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, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli*, etc.

Since many bacterial strains may be involved in otitis externa in dogs, the mechanisms of resistance can vary. The bacterial resistance phenotypes to gentamicin are mainly based on three mechanisms: enzymatic modification of aminoglycosides, failure of intracellular penetration of the active substance and alteration of the aminoglycoside target.
Cross-resistance is mainly linked with efflux pumps which confer resistance to β-lactams, quinolones and tetracyclines depending on the specificity of the pump with its substrate.
Co-resistance has been described, i.e. gentamicin resistance genes are found to be physically linked to other antimicrobial resistance genes that are transferred between pathogens due to transferable genetic elements such as plasmids, integrons and transposons.
Gentamicin resistant bacteria isolated from the field between 2008 and 2010 in canine otitis before treatment (determined according to CLSI guideline breakpoint ≥ 8 for all isolates except for

Staphylococci ≥ 16 µg/ml) were low: 4.7%, 2.9% and 12.5% for *Staphylococcus* spp., *Pseudomonas* and *Proteus* spp. respectively. All *Escherichia coli* isolates were fully susceptible to gentamicin.

4.3 Pharmacokinetics

After application of the veterinary medicinal product into the ear canal, absorption of miconazole and gentamicin through the skin is negligible.
Hydrocortisone aceponate belongs to the diesters' class of glucocorticosteroids. The diesters are lipophilic components ensuring an enhanced penetration into the skin associated with low systemic bioavailability. The diesters are transformed inside the skin structures in C17 monoesters responsible for the potency of the therapeutic class. In laboratory animals, hydrocortisone aceponate is eliminated the same way as hydrocortisone (other name for endogenous cortisol) through urine and faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Multi-dose container:
Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 10 days.

Single-dose container:
Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

5.3 Special precautions for storage

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

Multi-dose container:
Multi-dose container composed of two extruded parts, one external white polypropylene rigid tube and one internal (ethylene-methacrylic acid)-zinc copolymer (Surlyn) flexible pouch containing a steel ball, closed with a 1 ml dosing airless pump equipped with a flexible atraumatic cannula and covered by a plastic cap.
Box containing 1 multi-dose container (the content of 10 ml is equivalent to 10 doses).

Single-dose container:
Pipette composed of high density polyethylene (body and cannula) containing a steel ball.
Cardboard box containing 5, 10, 50, 100 or 200 pipettes.

Not all pack sizes may be marketed.

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

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/085/001–006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 20/11/2008.

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

{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

BOX OF 1 MULTI-DOSE CONTAINER OF 10 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Easotic ear drops, suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Hydrocortisone aceponate 1.11 mg/ml,
Miconazole as nitrate 15.1 mg/ml,
Gentamicin as sulphate 1,505 IU/ml.

3. PACKAGE SIZE

10 ml (10 doses).

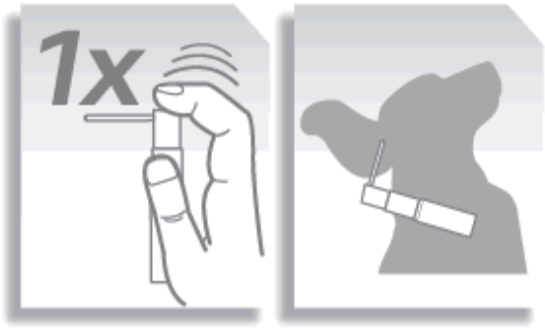
4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For auricular use only.



7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

EU/2/08/085/001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX OF 5, 10, 50, 100 or 200 PIPETTES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Easotic ear drops, suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Hydrocortisone aceponate 1.11 mg/ml,
Miconazole as nitrate 15.1 mg/ml,
Gentamicin as sulphate 1,505 IU/ml.

3. PACKAGE SIZE

1 dose x 5
1 dose x 10
1 dose x 50
1 dose x 100
1 dose x 200

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For auricular use only.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

EU/2/08/085/002 5 pipettes
EU/2/08/085/003 10 pipettes
EU/2/08/085/004 50 pipettes
EU/2/08/085/005 100 pipettes
EU/2/08/085/006 200 pipettes

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

MULTI-DOSE CONTAINER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Easotic

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Easotic

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Easotic ear drops, suspension for dogs

2. Composition

Hydrocortisone aceponate 1.11 mg/ml,
Miconazole as nitrate 15.1 mg/ml,
Gentamicin as sulphate 1,505 IU/ml.

A white suspension.

3. Target species

Dogs.

4. Indications for use

Treatment of acute otitis externa, and acute exacerbation of recurrent otitis externa associated with bacteria susceptible to gentamicin and fungi susceptible to miconazole in particular *Malassezia pachydermatis*.

5. Contraindications

Do not use in case 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 concurrently with substances known to cause ototoxicity.
Do not use in dogs with generalised demodicosis.

6. Special warnings

Special warnings:
Bacterial and fungal otitis is often secondary in nature and appropriate diagnosis should be used to determine the primary factors involved.

Special precautions for safe use in the target species:
If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted.
Use of the veterinary medicinal product should be based on identification of infecting organisms and susceptibility testing and take into account official and local antimicrobial policies.
Use of the veterinary medicinal product deviating from the instructions given in the summary of product characteristics may increase the prevalence of bacteria and fungi resistant to gentamicin and miconazole respectively and may decrease the effectiveness of treatment with aminoglycosides and azole antifungal agents, due to the potential for cross-resistance.
In case of parasitic otitis, an appropriate acaricidal treatment should be implemented.

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.
Gentamicin is known to be associated with ototoxicity when administered by the systemic route at higher doses.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental skin contact, it is recommended to wash thoroughly with water.
Avoid contact with eyes. In case of accidental contact, rinse with abundant quantities of water. In case of eye irritation, seek medical advice.
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.
Systemic absorption of hydrocortisone aceponate, gentamicin sulphate and miconazole nitrate being negligible, it is unlikely for teratogenic, foetotoxic or maternotoxic effects to occur at the recommended dosage in dogs.
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Compatibility with ear cleaners has not been demonstrated.

Overdose:
At 3 and 5 times the recommended dose, no local or general adverse reactions were observed with the exception of some dogs showing erythema and papulae in the ear canal.
In dogs treated at the therapeutic dose for ten consecutive days, serum cortisol levels decreased from five days onward and returned to normal values within ten days after the end of treatment. However, serum cortisol response levels post ACTH stimulation remained in the normal range during the extended treatment period, indicating a preserved adrenal function.

Major incompatibilities:
Do not mix with other veterinary medicinal products.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):
Application site reddening (ear) [1,2]
Uncommon (1 to 10 animals / 1,000 animals treated):
Application site papule [2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Impaired Hearing[3,4] ,Deafness [3,4] Hypersensitivity reactions (facial swelling, allergic pruritus) [4]

[1] Mild to moderate.
[2] Recovering without specific therapy.
[3] Primarily in geriatric dogs.

Complete recovery was confirmed in 70% of post marketing cases with an adequate follow-up, otherwise hearing improvement was observed in most dogs.
Recovery has been observed between one week and up to two months after onset of signs.
[4] If the adverse reaction occurs, treatment should be stopped.

Reporting adverse events is important. It allows continuous safety monitoring of a 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 or the local representative of 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

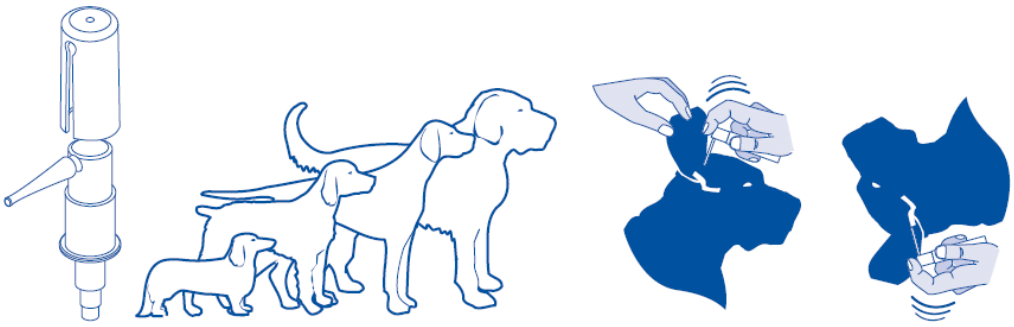
Auricular use. One ml contains 1.11 mg hydrocortisone aceponate, 15.1 mg miconazole (as nitrate) and 1,505 IU gentamicin (as sulphate).
It is recommended that the external ear canal should be cleaned and dried before treatment and excess hair around the treatment area be cut.

The recommended dosage is 1 ml of the veterinary medicinal product per ear once a day for five consecutive days.

[Multi-dose container:]
Shake the bottle thoroughly before first administration and prime the pump by pressing it.

Introduce the atraumatic canula in the ear canal. Administer one dose (1 ml) of the product in each affected ear. This dose is adequately delivered by one pump activation. The airless pump allows the product to be administered whatever the position of the bottle is.

1 dose / ear / day for 5 days



Whatever the size **Whatever the position**

The product as presented allows treating a dog suffering from bilateral otitis.

[Single-dose container:]
To administer one dose (1 ml) of the product in the affected ear:

- Take out one pipette from the box. Shake the pipette thoroughly before use.
- To open: hold up the pipette upright and break the top of the cannula.
- Introduce the atraumatic cannula in the ear canal. Squeeze gently but firmly in the middle of the body of the pipette.

9. Advice on correct administration

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.

The veterinary medicinal product should be used at room temperature (i.e. do not instil cold product).

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Do not use this veterinary medicinal product after the expiry date, which is stated on the label.
Shelf life after first opening the multi-dose container: 10 days.

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/2/08/085/001–006

Box containing 1 multi-dose container (the content of 10 ml is equivalent to 10 doses).
Cardboard box containing 5, 10, 50, 100 or 200 pipettes.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/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 manufacturer responsible for batch release:
VIRBAC
1ère avenue 2065 m LID
06516 Carros
France

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
VIRBAC BELGIUM NV
Esperantolaan 4
BE-3001 Leuven
Tél/Tel : +32-(0)16 387 260
phv@virbac.be

Република България
САМ БС ЕООД
Бул. "Д-р Петър Дертлиев" 25, Търговски център Лабиринт, ет. 5, офис САМ БС ЕООД
BG София 1335
Тел: +359 2 810 0173
sambs@sambs.bg

Česká republika
VIRBAC Czech Republic, s.r.o.
Žitavského 496
CZ 156 00 Praha 5
Tel: +420 608 836 529

Danmark
VIRBAC Danmark A/S
Profilvej 1
DK-6000 Kolding
Tlf.: +45 75521244
virbac@virbac.dk

Deutschland
VIRBAC Tierarzneimittel GmbH
Rögen 20
DE-23843 Bad Oldesloe
Tel: +49-(4531) 805 111

Eesti
OÜ ZOOVETVARU
Uusaru 5
EE-76505 Saue/Harjumaa
Tel: + 372 56480207
pv@zoovet.eu

Ελλάδα
VIRBAC ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.
13ο χλμ Ε.Ο. Αθηνών - Λαμίας
EL-14452, Μεταμόρφωση
Τηλ: +30 2106219520
info@virbac.gr

Lietuva
OÜ ZOOVETVARU
Uusaru 5
76505 Saue/Harjumaa
Estija
Tel: + 372 56480207
pv@zoovet.eu

Luxembourg/Luxemburg
VIRBAC BELGIUM NV
Esperantolaan 4
3001 Leuven
Belgique / Belgien
Tél/Tel: +32-(0)16 387 260
info@virbac.be

Magyarország
VIRBAC HUNGARY KFT
Dózsa György út 84. B épület
HU-1068 Budapest
Tel.: +36703387177
akos.csoman@virbac.hu

Malta
SEROLF TRADING AGENCY LTD.
8, Adelaide Cini Street
MT- PBK 1231 Pembroke
Tel: + 35621337231
info@serolf.com

Nederland
VIRBAC Nederland BV
Hermesweg 15
NL-3771 ND-Barneveld
Tel : +31-(0)342 427 127
phv@virbac.nl

Norge
VIRBAC Danmark A/S
Profilvej 1
6000 Kolding
Danmark
Tlf: + 45 75521244
virbac@virbac.dk

Österreich
VIRBAC Österreich GmbH
Hildebrandgasse 27
AT-1180 Wien
Tel: +43-(0)1-218 34 26-0

España
VIRBAC ESPAÑA SA
Angel Guimerá 179-181
ES-08950 Esplugues de Llobregat (Barcelona)
Tel : + 34-(0)93 470 79 40

France
VIRBAC France
13e rue LID
FR-06517 Carros
Tél : +33 800 73 09 10

Hrvatska
CENTRALNA VETERINARSKA AGENCIJA d.o.o. (CVA)
Prve Ravnice 2e,
HR-10000 Zagreb
Tel: + 385 91 46 55 112
kz@cva.hr

Ireland
VIRBAC IRELAND
McInerney & Saunders
38, Main Street
Swords, Co Dublin
K67E0A2 - IE
Tel: +44 (0)-1359 243243

Ísland
VISTOR HF.
Hörgatún 2,
IS-210 Garðabær
Sími: +354 535 7000
safety@vistor.is

Italia
VIRBAC SRL
Via Ettore Bugatti, 15
IT-20142 Milano
Tel: + 39 02 40 92 47 1

Κύπρος
ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.
13ο χλμ Ε.Ο. Αθηνών - Λαμίας
14452, Μεταμόρφωση
Ελλάδα
Τηλ.: +30 2106219520
info@virbac.gr

Polska
VIRBAC Sp. z o.o.
ul. Puławska 314
PL – 02-819 Warszawa
Tel.: + 48 22 855 40 46

Portugal
VIRBAC de Portugal Laboratórios LDA
Rua do Centro Empresarial
Edif13-Piso 1- Escrit.3
Quinta da Beloura
PT-2710-693 Sintra
Tel: + 351 219 245 020

România
ALTIUS SA
Str. Măgazului nr. 21-25, Corp A, et 8 si 8A
Ap. A.8.2, sect 1, București, cod 014261– RO
Tel: + 40 21 310 88 80

Slovenija
MEDICAL lNTERTRADE d.o.o.
Brodišče 12,
SI-1236 Trzin
Tel: + 386 1 2529 113
farmakovigilanca@medical-intertrade.si

Slovenská republika
VIRBAC Czech Republic, s.r.o.
Žitavského 496
156 00 Praha 5
Česká republika
Tel.: +420 608 836 529

Suomi/Finland
BIOFARM OY
Yrittäjäntie 20
FI-03600 Karkkila
Puh/Tel : +358-9-225 2560
mikko.koivu@biofarm.fi

Sverige
VIRBAC Danmark A/S Filial Sverige
Box 1027
SE-171 21 Solna
Tel: +45 75521244
virbac@virbac.dk

Latvija
OÜ ZOOVETVARU
Uusaru 5
76505 Saue/Harjumaa
Igaunija
Tel: + 372 56480207
pv@zoovet.eu

United Kingdom (Northern Ireland)
VIRBAC IRELAND
McInerney & Saunders
38, Main Street
Swords, Co Dublin
K67E0A2
Republic Of Ireland
Tel: +44 (0)-1359 243243

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

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