

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.

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear drops, suspension.
A white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the 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*.

4.3 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 demodecosis.

4.4 Special warnings

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

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

Mild to moderate redness of the ear was common (2.4% of treated dogs). Papules were observed uncommonly (less than 1% of treated dogs). In all cases, treatment with the veterinary medicinal product was not discontinued and all dogs recovered without any specific therapy.

In very rare cases, the use of the veterinary medicinal product has been associated with hearing impairment (partial hearing loss or deafness), primarily in geriatric dogs.

Based on post-marketing safety experience, hearing improvement was observed in most dogs with deafness/loss of hearing and complete recovery was confirmed in 70% of cases with an adequate follow-up.

Among dogs with full recovery, improvement has been rapidly seen. Recovery has been observed as early as one week after onset of signs, the majority of dogs recovering within one month; in a minority of reports, the deafness lasted for up to two months.

If deafness or partial hearing loss occurs, treatment should be stopped. See section 4.5 of the SPC.

In very rare cases, type-I hypersensitivity reactions (facial swelling, allergic pruritus) have been observed. If this occurs, treatment should be stopped.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 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.

4.8 Interaction with other medicinal products and other forms of interaction

Compatibility with ear cleaners has not been demonstrated.

4.9 Amounts to be administered and administration route

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.

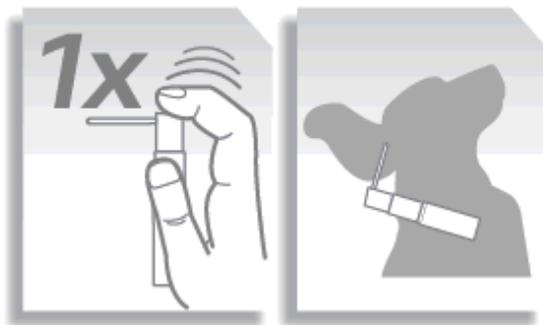
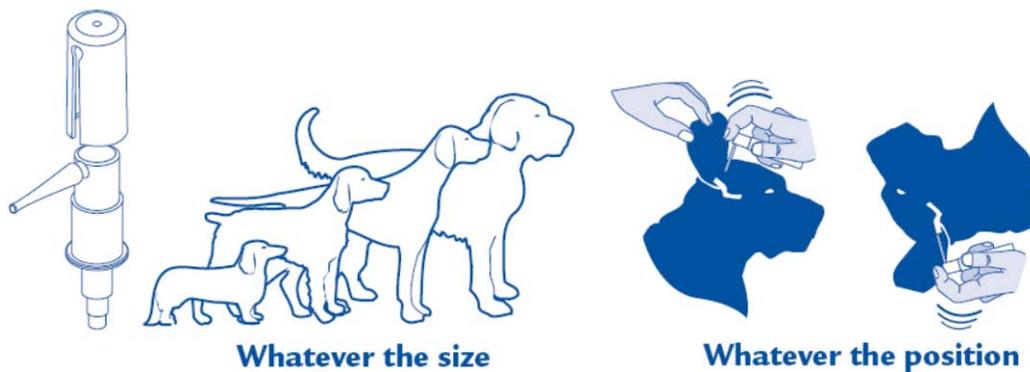
The recommended dosage is 1 ml of the veterinary medicinal product per infected ear once a day for five consecutive days.

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.

1 dose / ear / day for 5 days



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).

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

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.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Otologicals, corticosteroids and antiinfectives in combination.
ATCvet code: QS02CA03.

5.1 Pharmacodynamic properties

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 $\mu\text{g/ml}$) 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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin.

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 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.

6.4. Special precautions for storage

Do not store above 25°C.

6.5 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.

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

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

7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065 m LID
06516 Carros

FRANCE
Tel.: 0033/4.92.08.73.00
Fax: 0033/4.92.08.73.48
E-mail: dar@virbac.fr

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/085/001-006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20/11/2008.

Date of first renewal: 11/11/2013.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

VIRBAC
1^{ère} avenue 2065 m LID
06516 Carros
FRANCE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

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 for dogs
Hydrocortisone aceponate - Miconazole – Gentamicin

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. PHARMACEUTICAL FORM

Ear drops, suspension.

4. PACKAGE SIZE

10 ml (10 doses).

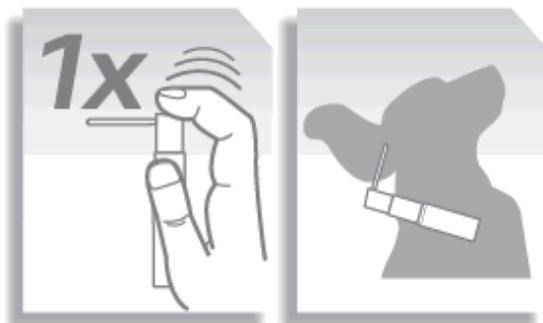
5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For auricular use only.
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 {month/year}

Once opened use within 10 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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. To be supplied only on veterinary prescription.

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

VIRBAC
1^{ère} avenue 2065 m LID
06516 Carros
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/085/001

17. MANUFACTURER’S 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 for dogs
Hydrocortisone aceponate - Miconazole – Gentamicin

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. PHARMACEUTICAL FORM

Ear drops suspension.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For auricular use only.

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 {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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. To be supplied only on veterinary prescription.

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

VIRBAC
1^{ère} avenue 2065 m LID
06516 Carros
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/085/002
EU/2/08/085/003
EU/2/08/085/004
EU/2/08/085/005
EU/2/08/085/006

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
MULTI-DOSE CONTAINER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Easotic ear drops, suspension for dogs
Hydrocortisone aceponate - Miconazole – Gentamicin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

10 ml (10 doses).

4. ROUTE(S) OF ADMINISTRATION

Auricular use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use within 10 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PIPETTE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Easotic



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

1 ml

4. ROUTE(S) OF ADMINISTRATION

(Reference is made to the drawing in section 1)

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
(Reference is made to the drawing in section 1)

B. PACKAGE LEAFLET

PACKAGE LEAFLET :
Easotic 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 and manufacturer responsible for batch release:

VIRBAC
1^{ère} avenue 2065 m LID
06516 Carros
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Easotic ear drops, suspension for dogs

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

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

4. INDICATION(S)

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

Do not use if the eardrum is perforated.

Do not use concurrently with substances known to cause ototoxicity.

6. ADVERSE REACTIONS

Mild to moderate redness of the ear was common (2.4% of treated dogs). Papules were observed uncommonly (less than 1% of treated dogs). In all cases, treatment with the veterinary medicinal product was not discontinued and all dogs recovered without any specific therapy.

In very rare cases, the use of the veterinary medicinal product has been associated with hearing impairment (partial hearing loss or deafness), primarily in geriatric dogs.

Based on post-marketing safety experience, hearing improvement was observed in most dogs with deafness/loss of hearing and complete recovery was confirmed in 70% of cases with an adequate follow-up.

Among dogs with full recovery, improvement has been rapidly seen. Recovery has been observed as early as one week after onset of signs, the majority of dogs recovering within one month; in a minority of reports, the deafness lasted for up to two months.

If deafness or partial hearing loss occurs, treatment should be stopped. See also “Special precautions for use in animals”.

In very rare cases, Type-I Hypersensitivity reactions (facial swelling, allergic pruritus) have been observed. If this occurs, treatment should be stopped.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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. 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.

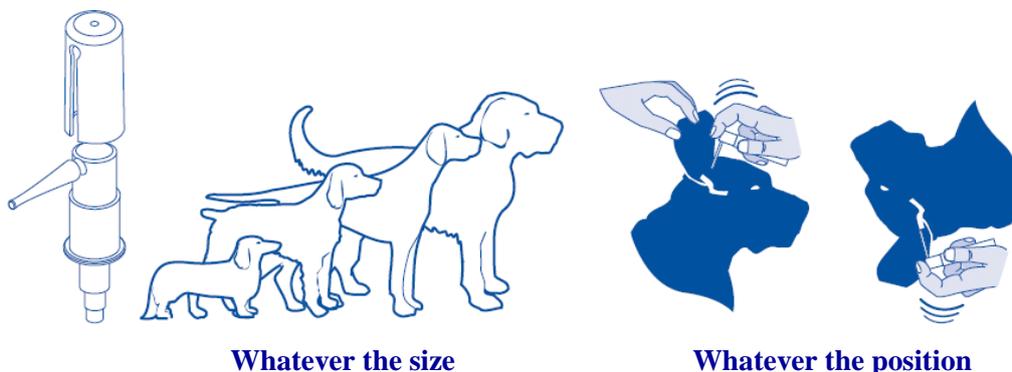
The recommended dosage is 1 ml of the veterinary medicinal product per ear once a day for five consecutive days.

[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



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 PERIOD(S)

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 WARNING(S)

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 use in animals:

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 (symptoms, emergency procedures, 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.

Incompatibilities:

Do not mix with other veterinary medicinal products.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

15. OTHER INFORMATION

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

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

België/Belgique/Belgien

VIRBAC BELGIUM NV
Esperantolaan 4
BE-3001 Leuven
Tél/Tel : +32-(0)16 387 260

Lietuva

VIRBAC
1^{ère} avenue 2065 m LID
FR-06516 Carros
Prancūzija
Tel: +33-(0)4 92 08 73 00

Република България

VIRBAC
1^{ère} avenue 2065 m LID
FR-06516 Carros
Франция
Тел: +33-(0)4 92 08 73 00

Luxembourg/Luxemburg

VIRBAC BELGIUM NV
Esperantolaan 4
BE-3001 Leuven
Belgique / Belgien
Tél/Tel: +32-(0)16 387 260

Česká republika

VIRBAC
1^{ère} avenue 2065 m LID
FR-06516 Carros
Francie
Tel: +33-(0)4 92 08 73 00

Danmark

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

Deutschland

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

Eesti

VIRBAC
1^{ère} avenue 2065 m LID
FR-06516 Carros
Prantsusmaa
Tel: +33-(0)4 92 08 73 00

Ελλάδα

VIRBAC HELLAS A.E.
13^ο χλμ Ε.Ο. Αθηνών - Λαμίας
EL-14452, Μεταμόρφωση
Τηλ: +30 2106219520

España

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

France

VIRBAC France
13^e rue LID
FR-06517 Carros
Tél : +33 805 05 55 55

Hrvatska

VIRBAC
1^{ère} avenue 2065 m LID
FR-06516 Carros
Francuska
Tel: + 33-(0)4 92 08 73 00

Magyarország

VIRBAC HUNGARY KFT
Szent István krt.11.II/21.
HU-1055 Budapest
Tel: +36703387177

Malta

VIRBAC
1^{ère} avenue 2065 m LID
FR-06516 Carros
Franza
Tel: + 33-(0)4 92 08 73 00

Nederland

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

Norge

VIRBAC Danmark A/S
Profilvej 1
DK-6000 Kolding
Danmark
Tel: + 45 75521244

Österreich

VIRBAC Österreich GmbH
Hildebrandgasse 27
A-1180 Wien
Tel: +43-(0)1 21 834 260

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
R.do Centro Empresarial
Ed13-Piso 1- Esc.3
Quinta da Beloura
PT-2710-693 Sintra
Tel: + 351 219 245 020

România

VIRBAC
1^{ère} avenue 2065 m LID
FR-06516 Carros
Franța
Tel: + 33-(0)4 92 08 73 00

Ireland

VIRBAC

1^{ère} avenue 2065m LID

FR-06516 Carros

France

Tel: + 33-(0)4 92 08 73 00

Ísland

VIRBAC

1^{ère} avenue 2065 m LID

FR-06516 Carros

Frakkland

Sími: + 33-(0)4 92 08 73 00

Italia

VIRBAC SRL

Via Ettore Bugatti, 15

IT-20142 Milano

Tel: + 39 02 40 92 47 1

Κύπρος

VIRBAC HELLAS A.E.

13^ο χλμ Ε.Ο. Αθηνών - Λαμίας

EL-14452, Μεταμόρφωση

Τηλ.: +30 2106219520

Latvija

VIRBAC

1^{ère} avenue 2065 m LID

FR-06516 Carros

Francija

Tel: +33-(0)4 92 08 73 00

Slovenija

VIRBAC

1^{ère} avenue 2065 m LID

FR-06516 Carros

Francija

Tel : + 33-(0)4 92 08 73 00

Slovenská republika

VIRBAC

1^{ère} avenue 2065 m LID

FR-06516 Carros

Francúzsko

Tel: + 33-(0)4 92 08 73 00

Suomi/Finland

VIRBAC

1^{ère} avenue 2065 m LID

FR-06516 Carros

Puh/Tel : + 33-(0)4 92 08 73 00

Sverige

VIRBAC Danmark A/S Filial Sverige

c/o Incognito AB

Box 1027

SE-171 21 Solna

Tel: +45 75521244

United Kingdom (Northern Ireland)

VIRBAC

1^{ère} avenue 2065m LID

FR-06516 Carros

France

Tel: + 33-(0)4 92 08 73 00