

**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 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 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, usually temporary, and primarily in geriatric dogs. If this 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 displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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.

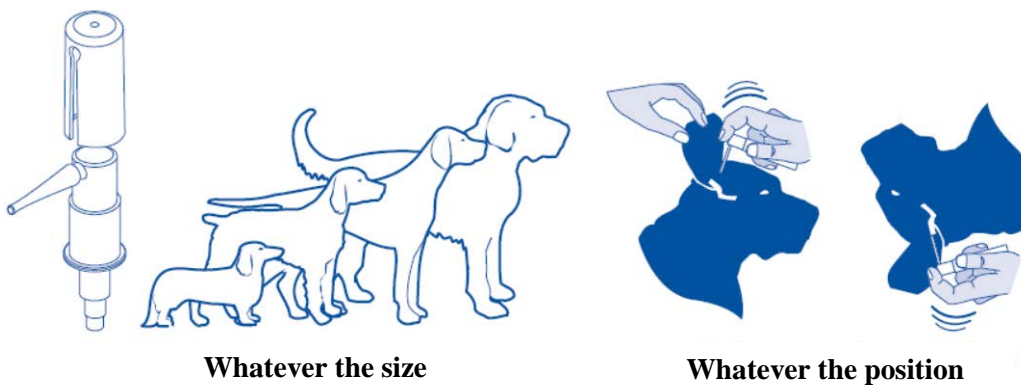
The recommended dosage is 1 ml of the veterinary medicinal product per infected ear once a day for five consecutive days.

Multi-dose container:

Shake the bottle thoroughly before first administration and prime the pump.

Introduce the atraumatic cannula 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  $\beta$ -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  $\geq 8$  for all isolates except for *Staphylococci*  $\geq 16$   $\mu\text{g/ml}$ ) 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 Incompatibilities**

Do not mix with other veterinary medicinal products.

### **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 L.I.D.

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<sup>ère</sup> avenue 2065 m L.I.D.  
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 AND OTHER 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**

**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<sup>ère</sup> avenue 2065 m L.I.D.  
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 AND OTHER 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**

**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<sup>ère</sup> avenue 2065 m L.I.D.  
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**

**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**

**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 FOR:  
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<sup>ère</sup> avenue 2065 m L.I.D.  
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, usually temporary, and primarily in geriatric dogs. In this case, 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 displaying adverse reaction(s) during the course of one treatment)

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

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

## 7. TARGET SPECIES

Dogs.

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

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.

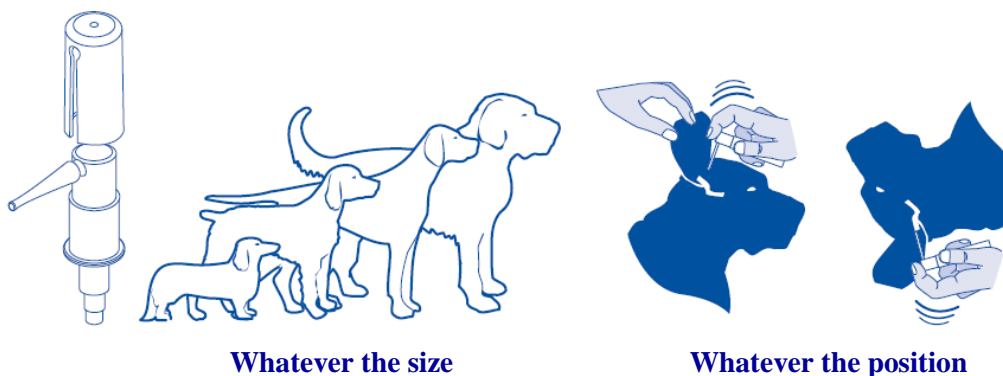
The recommended dosage is 1 ml of the veterinary medicinal product per ear once a day for five consecutive days.

[Multi-dose container:]

Shake the bottle thoroughly before first administration and prime the pump.

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

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 N.V.  
Esperantolaan 4  
3001 Leuven  
Tel: 32 (0) 16 38 72 60

**Република България**  
VIRBAC  
1<sup>ère</sup> avenue 2065 m – L.I.D  
06516 Carros  
FRANCE  
Tel: 33 (0) 4 92 08 73 00

**Luxembourg/Luxemburg**  
VIRBAC BELGIUM N.V.  
Esperantolaan 4  
3001 Leuven  
BELGIUM  
Tel: 32 (0) 16 38 72 60

**Magyarország**  
VIRBAC  
1<sup>ère</sup> avenue 2065 m – L.I.D  
06516 Carros  
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Tel: 33 (0) 4 92 08 73 00

**Česká republika**

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Tlf. : + 45 75521244

**Deutschland**

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Rögen 20  
23843 Bad Oldesloe  
Tel: 49 (4531) 805 111

**Eesti**

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Uusaru 5  
76505 Saue/Harjumaa  
Tel: + 372 6 709 006

**Ελλάδα**

VIRBAC HELLAS A.E.  
23 rd Klm National Road Athens-Lamia  
14565 Agios Stefanos (Athens)  
Tel: 30 210 6219520

**España**

VIRBAC ESPAÑA, S.A.  
C/Angel Guimera 179-181-  
08950 - Esplugues de Llobregat (Barcelona)  
Tel: 34 (93) 470 79 40

**France**

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13<sup>ème</sup> rue – L.I.D – BP 27  
06517 Carros

**Ireland**

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UK-Suffolk IP30 9 UP  
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**Malta**

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1<sup>ère</sup> avenue 2065 m – L.I.D  
06516 Carros  
FRANCE  
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**Nederland**

VIRBAC NEDERLAND BV  
Hermesweg 15  
3771 ND-Barneveld  
Tel.: 31 (0) 342 427 100

**Norge**

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c/o Premium Pet Products  
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0614 Oslo  
Tel: + 45 7552 1244

**Österreich**

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1180 Wien  
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ul. Puławska 314  
02-819 Warszawa

**Portugal**

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2710-693 Sintra  
00 351 219 245 020

**România**

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