PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cortotic 0.584 mg/ml ear spray solution for dogs

Hydrocortisone aceponate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 0.584 mg of hydrocortisone aceponate.

3. PACKAGE SIZE

16 ml

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Auricular use.

7. WITHDRAWAL PERIODS

Not applicable.

8. EXPIRY DATE

EXP {MM/AAAA}

Once opened, use by: …….

9. SPECIAL STORAGE PRECAUTIONS

Store below 25ºC

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

14. MARKETING AUTHORISATION NUMBER

Vm 05653/5041

15. BATCH NUMBER

Batch {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V (‘To be supplied only on veterinary prescription’)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {HDPE BOTTLE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cortotic 0.584 mg/ml ear spray solution for dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Hydrocortisone aceponate 0.584 mg/ml

3. BATCH NUMBER

Batch {number}

4. EXPIRY DATE

EXP {MM/AAAA}

Once opened, use by.

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

16 ml

6. ROUTE(S) OF ADMINISTRATION

Auricular use.

7. WITHDRAWAL PERIOD

Not applicable.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cortotic 0.584 mg/ml ear spray solution for dogs

2. COMPOSITION

Each ml contains:

Active substance:
Hydrocortisone aceponate 0.584 mg

Excipient:
Propylene glycol methyl ether

Clear colourless or slightly coloured solution.

3. TARGET SPECIES

Dogs

4. INDICATIONS FOR USE

For the treatment of clinical signs associated with acute erythroceruminous otitis externa.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance, to other corticosteroids or to any of the excipients.

Do not use in animals with perforated tympanic membrane.

Do not use on cutaneous ulcers.

6. SPECIAL WARNING(S)

For Animal Treatment Only

Keep out of the sight and reach of children.

In the clinical field trial, an ear cleanser was used for cleaning the ears before the first product application.

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

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

In the clinical field trial, 201 dogs were included diagnosed with acute erythroceruminous otitis externa, all with the presence of bacterial and/or yeast overgrowth. It was demonstrated that the veterinary medicinal product was non-inferior in treating acute otitis compared to a topic fixed-combination product containing a corticosteroid, an antibiotic and an antimycotic as active substances. A secondary reduction of bacterial and yeast overgrowth was demonstrated and a concomitant treatment with an antimicrobial was unnecessary.

Special precautions for safe use in the target species:

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.

Avoid contact with dog's eyes by restraining the dog's head to prevent shaking. In case of accidental contact, rinse thoroughly with water.

Safety and efficacy have not been assessed in dogs under 4 months of age or weighing less than 2.8 kg. In these cases, the product should be used according to a benefit/risk assessment by the veterinarian.

In the absence of specific information, the use in animals suffering from Cushing's syndrome or with a suspected or confirmed endocrine disorder (e.g. diabetes mellitus) or with generalised demodicosis shall be based on the risk-benefit assessment.

The product has not been assessed in suppurative otitis externa. Use only according to the benefit-risk assessment by the responsible veterinarian.

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

The product is an eye irritant. Avoid contact with eyes including hand-to-eye contact. In case of accidental eye contact, rinse with large quantities of water. In case of eye irritation, seek medical advice immediately and show the leaflet or the label to the physician.
This active substance is potentially pharmacologically active at high doses of exposure. Avoid skin contact. Avoid oral exposure (including hand-to-mouth contacts). Replace the bottle in the outer carton and store in a safe place out of the sight and reach of children.
In case of accidental ingestion, particularly by children, seek medical advice immediately and show the leaflet or the label to the physician.
In case of accidental skin contact, it is recommended to wash thoroughly with water.
The product may have effects on the foetus if absorbed through the skin or ingested. Wash hands after use.
The product is flammable. Do not spray on naked flame or any incandescent material. Do not smoke while handling the product.

Other precautions:

The solvent in this product may stain certain materials including painted, vanished, or other household surfaces of furnishings.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Systemic absorption of hydrocortisone aceponate being negligible, it is unlikely for teratogenic, foetotoxic, maternotoxic effects to happen at the recommended dosage in dogs.

Use only according to the risk-benefit assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

None.

Overdose:

In an overdose study in 4-month-old puppies, reversible and non-adverse reduction of the capacity for production of cortisol (temporary suppression of the adrenal function) was reported after repeated ear administration at 3 times the therapeutic dose or 3 times the treatment duration.

7. ADVERSE EVENTS

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Tympanic opacity (Transient white opaque areas in the tympanic membrane with no impaired hearing or deafness were observed in a laboratory study.)

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.

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

Auricular use.

The recommended dosage is 0.44 ml of the veterinary medicinal product per affected ear once a day for 7 consecutive days. This dose is adequately delivered by two pump activations.

If the condition is not considered completely cured by the veterinarian within 7 days, treatment may be extended until 14 days. The maximum clinical response may not be seen until 28 days after the first administration.

9. ADVICE ON CORRECT ADMINISTRATION

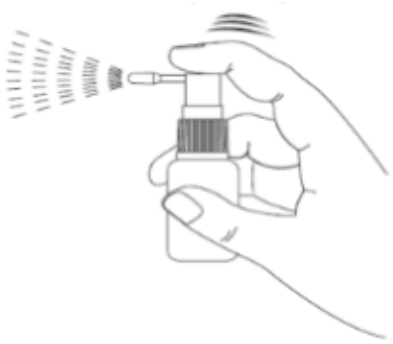
Instructions for proper use:

It is recommended that the external ear canal should be cleaned and dried before the first treatment.
It is recommended not to repeat ear cleaning before further applications.
Before first administration, remove the cap and screw the spray pump on the bottle.
Then prime the pump by pressing it until the product is released.
Introduce the atraumatic cannula in the ear canal. Hold the product upright while administering the product in the affected ear(s). After each application massage the ear and auditory canal gently but thoroughly to ensure proper distribution.
Keep the pump screwed after use.
If the pump has not been used for a long time, activate it once before you apply the spray again.
The volume of the bottle allows the treatment of 2 ears for 14 days.

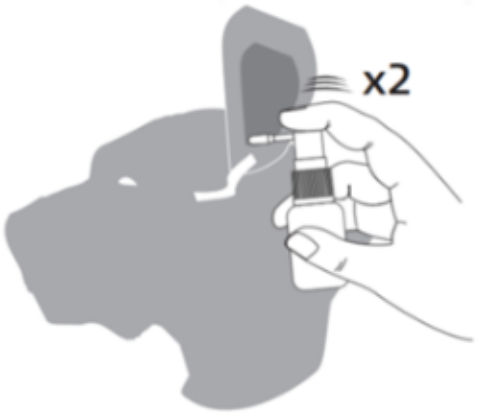
1 - Unscrew the overcap.

2 6 Screw the spray pump on the bottle.

3 - Then prime the pump by pressing on it until the product dispenses.



4 - Introduce the atraumatic cannula into the ear canal. Hold the bottle as upright as possible while administering the required dose of the product into the ear or affected ears.



This dose is adequately delivered by two pump activations (fully press down on the pump for each activation).

After each application massage the ear and auditory canal gently but thoroughly to ensure proper distribution.

Do not tilt the bottle 

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 25ºC
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 6 months.

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 05653/5041

Package sizes: Box with 1 bottle and 1 spray pump.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:
VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Local representative and contact details to report suspected adverse reactions:
Virbac Ltd.
Woolpit Business Park
Windmill Avenue, Woolpit
Bury St. Edmunds
Suffolk
IP30 9UP
Tel.: +44 (0)1359 243243

17. OTHER INFORMATION

Gavin Hall

Approved: 30 May 2024