SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cortotic 0.584 mg/ml ear spray solution for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Hydrocortisone aceponate 0.584 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ear spray solution

Clear colourless or slightly coloured solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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.

Special precautions for the protection of environment:
Not Applicable.

Other precautions

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

4.6 Adverse reactions (frequency and seriousness)

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.)

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for contact details.

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 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.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amount(s) to be administered and administration route

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.

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 and apply the product by two pump activations. 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.

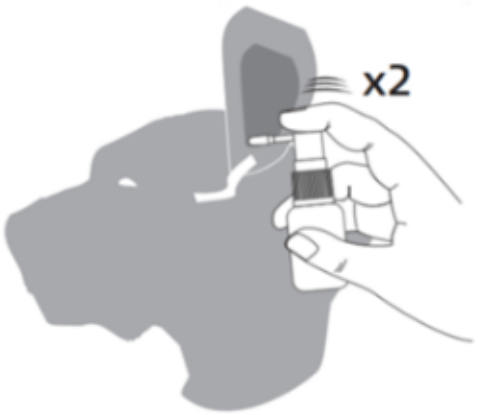
The volume of the bottle allows the treatment of 2 ears for 14 days.

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 

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Otologicals, corticosteroids.

ATC Vet Code: QS02BA01.

5.1 Pharmacodynamic properties

The veterinary medicinal product contains the active substance hydrocortisone aceponate.

Hydrocortisone aceponate (HCA) belongs to the diester class of the glucocorticosteroids with a potent intrinsic glucocorticoid activity. The product relieves both inflammation and pruritus which leads to an improvement of clinical signs of otitis externa and a reduction of bacteria and yeast overgrowth.

5.2 Pharmacokinetic particulars

HCA is a lipophilic component ensuring an enhanced penetration into the skin associated with a low plasma availability and systemic exposure. After topical or auricular administration, HCA accumulates slightly in the dog's skin, in the dermis and hypodermis of the dog's ear canal. HCA is transformed inside the skin structures. This transformation is responsible for the potency of the therapeutic class. In laboratory animals, HCA is eliminated the same way as hydrocortisone (other name for endogenous cortisol) through urine and faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol methyl ether.

6.2 Major Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after first opening the immediate packaging: 6 months.

6.4 Special precautions for storage

Store below 25ºC.

6.5 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottle of 20 ml filled with 16 ml of solution, closed with an HDPE screw cap and an HDPE spray pump.

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

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/5041

9. DATE OF FIRST AUTHORISATION

30 May 2024

10. DATE OF REVISION OF THE TEXT

April 2025

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Gavin Hall

Approved 01 May 2025