

Cortotic 0.584 mg/ml ear spray, solution for dogs

Authorised

- Hydrocortisone aceponate

Product identification

Medicine name:

Cortotic 0.584 mg/ml ear spray, solution for dogs

Active substance:

Hydrocortisone aceponate

Target species:

Dog

Route of administration:

Auricular use

Product details

Active substance and strength:

Hydrocortisone aceponate
0.58 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Ear spray, solution

Withdrawal period by route of administration:

Auricular use:

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Dog

- Not applicable. no withdrawal period Not applicable

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QS02BA01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Austria

Available in:

Austria

Package description:

Box with 1 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.

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:

Virbac

Marketing authorisation date:

9/01/2023

Manufacturing sites for batch release:

Virbac S.A.

Responsible authority:

Austrian Agency For Health And Food Safety

Authorisation number:

841530

Date of authorisation status change:

9/01/2023

Reference member state:

Netherlands

Procedure number:

NL/V/0370/001

Concerned member states:

Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland
France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania
Luxembourg Norway Poland Portugal Romania Slovakia Slovenia Spain
Sweden

To consult adverse reactions on veterinary medicinal products please go to
www.adrreports.eu/vet

Documents

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Labelling

This document does not exist in this language (English). You can find it in another language below.