

Otisan 3 mg/ml + 10 mg/ml + 1 mg/ml ear drops, suspension for dogs

Authorised

- Marbofloxacin
- Clotrimazole
- Dexamethasone acetate

Product identification

Medicine name:

Otisan 3 mg/ml + 10 mg/ml + 1 mg/ml ear drops, suspension for dogs

Active substance:

Marbofloxacin

Clotrimazole

Dexamethasone acetate

Target species:

Dog

Route of administration:

Auricular use

Product details

Active substance and strength:

Marbofloxacin

3.00 milligram(s) / 1.00 millilitre(s)

Clotrimazole

10.00 milligram(s) / 1.00 millilitre(s)

Dexamethasone acetate

1.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Ear drops, suspension

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QS02CA06

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Slovakia

Available in:

Slovakia

Package description:

Cardboard box with 1 bottle of 15 ml

Cardboard box with 1 bottle of 25 ml.

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Hybrid application - change in active substance(s) (Article 19(1)(a) of Regulation (EU) 2019/6)

Marketing authorisation holder:

Przedsiębiorstwo Wielobranzowe Vet-Agro Sp. z o.o.

Marketing authorisation date:

29/05/2024

Manufacturing sites for batch release:

Przedsiębiorstwo Wielobranzowe Vet-Agro Sp. z o.o.

Responsible authority:

Institute For State Control Of Veterinary Biologicals And Medicaments

Authorisation number:

96/006/DC/24-S

Date of authorisation status change:

29/05/2024

Reference member state:

Spain

Procedure number:

ES/V/0425/001

Concerned member states:

Belgium Bulgaria Croatia Czechia Greece Ireland Italy Lithuania

Netherlands Poland Portugal Romania Slovakia

United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to

www.adrreports.eu/vet

Documents

Combined File of all Documents

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

Summary of Product Characteristics

Package Leaflet

Labelling