

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

Authorised

- Marbofloxacin
- Clotrimazole
- Dexamethasone acetate

Product identification

Medicine name:

Marbotis 3mg/ml + 10mg/ml + 1mg/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:

Ireland

Available in:

Ireland

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:

15/03/2024

Manufacturing sites for batch release:

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

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA20742/010/001

Date of authorisation status change:

15/03/2024

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

Summary of Product Characteristics

Package Leaflet

Labelling

Combined File of all Documents