Osurnia 10 mg/10 mg/1 mg - Ear gel

Authorised

- Terbinafine
- Florfenicol
- Betamethasone acetate

Product identification

Medicine name:
Osurnia 10 mg/10 mg/1 mg - Ear gel

Active substance:
Terbinafine

Florfenicol

Betamethasone acetate

Target species:
Dog

Route of administration:
Auricular use

Product details

Active substance and strength:
Terbinafine

10.00 milligram(s) / 1.00 Tube

Florfenicol
10.00 milligram(s) / 1.00 Tube

Betamethasone acetate
1.00 milligram(s) / 1.00 Tube

Pharmaceutical form:
Ear gel

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QS02CA90

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Austria , Belgium , Bulgaria , Croatia , Cyprus , Czechia , Denmark , Estonia , Finland , France , Germany , Greece , Hungary , Iceland , Ireland , Italy , Latvia , Liechtenstein , Lithuania , Luxembourg , Malta , Netherlands , Norway , Poland , Portugal , Romania , Slovakia , Slovenia , Spain , Sweden , United Kingdom (Northern Ireland)

Available in:
Austria , Belgium , Bulgaria , Croatia , Cyprus , Czechia , Denmark , Estonia , Finland , France , Germany , Greece , Hungary , Ireland , Italy , Latvia , Lithuania , Malta , Netherlands , Norway , Poland , Portugal , Romania , Slovenia , Spain , Sweden

Package description:
Packaging:Tube (Alu/PE) with PP elastomer tip, Package_size:40 tubes, Content:2,05 g
Packaging:Tube (Alu/PE) with PP elastomer tip, Package_size:20 tubes, Content:2,05 g
Packaging:Tube (Alu/PE) with PP elastomer tip, Package_size:12 tubes, Content:2,05 g
Packaging:Tube (Alu/PE) with PP elastomer tip, Package_size:2 tubes, Content:2,05 g

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application - New active substance (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Dechra Regulatory B.V.

Marketing authorisation date:
31/07/2014

Manufacturing sites for batch release:
Argenta Dundee Limited
Genera d.d.

Responsible authority:
European Commission

Authorisation number:
This information is not available for this product.

Date of authorisation status change:
31/07/2014

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

Documents

Combined File of all Documents

English (PDF)
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