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OTOMAX EAR DROPS SUSPENSION

Authorised

- Gentamicin sulfate
- Clotrimazole
- Betamethasone valerate

Product identification

Medicine name:
OTOMAX EAR DROPS SUSPENSION

Active substance:
Gentamicin sulfate

Clotrimazole

Betamethasone valerate

Target species:
Dog

Route of administration:
Auricular use

Product details

Active substance and strength:
Gentamicin sulfate

2640.00 international unit(s) / 1.00 millilitre(s)

Clotrimazole
8.80 milligram(s) / 1.00 millilitre(s)

Betamethasone valerate
1.07 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Ear drops, suspension

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QS02CA90

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

Authorisation status:
Valid

Authorised in:
Denmark

Available in:
Denmark

Package description:
Available only in French
Available only in French
Available only in French
Available only in French
Available only in French
Available only in French
Available only in French
Available only in French

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Legal basis not covered by Directive 2001/82/EC

Marketing authorisation holder:
Intervet International B.V.

Marketing authorisation date:
30/07/1999

Manufacturing sites for batch release:
Trirx Segre

Responsible authority:
Danish Medicines Agency

Authorisation number:
30828

Date of authorisation status change:
30/07/1999

Reference member state:
France

Procedure number:
FR/V/0110/001

Concerned member states:
Austria Belgium Denmark Finland Germany Greece Ireland Italy Luxembourg Portugal Spain Sweden United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

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Combined File of all Documents