

# OTOMAX EAR DROPS SUSPENSION

Authorised

- Gentamicin sulfate
- Clotrimazole
- Betamethasone valerate

## Product identification

**Medicine name:**

OTOMAX EAR DROPS SUSPENSION

OTOMAX, ωτικές σταγόνες εναιώρημα

**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)

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**Pharmaceutical form:**

Ear drops, suspension

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QS02CA90

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Greece

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**Package description:**

Box containing 1 tube of 8.5 ml  
Box containing 12 tubes of 17 ml  
Box containing 12 tubes of 8.5 ml  
Box containing 6 tubes of 17 ml  
Box containing 6 tubes of 8.5 ml  
Box containing 1 bottle of 34 ml  
Box containing 1 bottle of 14 ml  
Box containing 1 tube of 17 ml

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Legal basis not covered by Directive 2001/82/EC

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**Marketing authorisation holder:**

Intervet Hellas M.A.E.

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**Marketing authorisation date:**

18/08/1999

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**Manufacturing sites for batch release:**

Trirx Segre

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**Responsible authority:**

National Organization For Medicines

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**Authorisation number:**

36525/19-05-2011/K-0133201

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**Date of authorisation status change:**

2/06/2021

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**Reference member state:**

France

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**Procedure number:**

FR/V/0110/001

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**Concerned member states:**

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

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

### Summary of Product Characteristics

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

### Package Leaflet

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