

Osphos 51 mg/ml solution for injection for horses

Authorised

- Clodronate disodium tetrahydrate

Product identification

Medicine name:

Osphos 51 mg/ml solution for injection for horses

Active substance:

Clodronate disodium tetrahydrate

Target species:

Horse

Route of administration:

Intramuscular use

Product details

Active substance and strength:

Clodronate disodium tetrahydrate
74.98 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:**Intramuscular use:**

-

Horse

- Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QM05BA02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Iceland

Available in:

Iceland

Package description:

Clear glass (type I) vial with siliconized rubber stopper, an aluminium seal and a plastic flip-off cap containing 15 ml of clodronic acid solution. Each cardboard box contains 1 vial

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:

Dechra Regulatory B.V.

Marketing authorisation date:

23/06/2015

Manufacturing sites for batch release:

Eurovet Animal Health B.V.

Responsible authority:

Icelandic Medicines Agency

Authorisation number:

IS/2/15/013/01

Date of authorisation status change:

1/09/2021

Reference member state:

Ireland

Procedure number:

IE/V/0508/001

Concerned member states:

Austria Belgium Czechia Finland France Germany Hungary Iceland Italy
Luxembourg Netherlands Poland Portugal Slovakia 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

Combined File of all Documents

English (PDF)

Published on: 26/01/2025

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Package Leaflet

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