Rapidexon 2 mg/ml solution for injection

• Dexamethasone sodium phosphate

Product identification

Medicine name:

Rapidexon 2 mg/ml solution for injection Rapidexon 2 mg/ml roztwór do wstrzykiwań

Active substance:

Dexamethasone sodium phosphate

Target species:

Horse Cattle

Pig

Dog

Cat

Route of administration:

Intraarticular use Intramuscular use Intravenous use Intrabursal use

Product details

Active substance and strength:

Dexamethasone sodium phosphate 2.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration: Intraarticular use:

Horse

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- Meat and offal. 8 day

Intramuscular use:

Cattle

- Milk. 72 hour
- Meat and offal. 8 day

Pig

- Meat and offal. 2 day

Horse

- Meat and offal. 8 day

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Dog

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Cat

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Intravenous use:

Horse

- Meat and offal. 8 day

Intrabursal use:

Horse

- Meat and offal. 8 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QH02AB02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in: Poland

Package description:

50 ml vial glass type I uncoloured with bromobutyl rubber stopper type I secured with aluminium cap

25 ml vial (filled in 30 ml vial) glass type I uncoloured with bromobutyl rubber stopper type I secured with aluminium cap

100 ml vial glass type I uncoloured with bromobutyl rubber stopper type I secured with aluminium

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:

Eurovet Animal Health B.V.

Marketing authorisation date:

20/10/2008

Manufacturing sites for batch release:

Eurovet Animal Health B.V.

Responsible authority:

Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

Authorisation number:

1847

Date of authorisation status change:

20/10/2008

Reference member state:

Netherlands

Procedure number:

NL/V/0284/001

Concerned member states:

Austria Belgium Czechia Denmark Finland France Greece Hungary Ireland Lithuania Poland Portugal Slovakia Slovenia Spain

United Kingdom (Northern Ireland)

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

Documents

Labelling

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.

Combined File of all Documents

Summary of Product Characteristics

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

Rapidexon 2 mg.pdf

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