

Dexa-ject 2 mg/ml solution for injection for cattle, horses, pigs, dogs and cats

Authorised

- Dexamethasone sodium phosphate

Product identification

Medicine name:

Dexa-ject 2 mg/ml solution for injection for cattle, horses, pigs, dogs and cats

Active substance:

Dexamethasone sodium phosphate

Target species:

Horse
Cattle
Dog
Cat
Pig

Route of administration:

Intraarticular use
Intramuscular use
Intravenous use

Product details

Active substance and strength:

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

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Intraarticular use:

-

Horse

- Meat and offal. 8 day

Intramuscular use:

-

Cattle

- Meat and offal. 8 day

- Milk. 72 hour

-

Horse

- Meat and offal. 8 day

-

Pig

- Meat and offal. 2 day

Intravenous 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:

Norway

Available in:

Norway

Package description:

Cardboard box with 1 colourless, type I glass vial of 100 ml which is closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

Cardboard box with 1 colourless, type I glass vial of 50 ml which is closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

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:

Dopharma Research B.V.

Marketing authorisation date:

31/05/2018

Manufacturing sites for batch release:

Dopharma B.V.

Responsible authority:

Norwegian Medical Products Agency

Authorisation number:

17-11960

Date of authorisation status change:

20/02/2019

Reference member state:

Ireland

Procedure number:

IE/V/0293/001

Concerned member states:

Austria Belgium Bulgaria Croatia Czechia Denmark Estonia Finland France
Germany Greece Hungary Iceland Italy Latvia Lithuania Netherlands
Norway Poland Romania 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

English (PDF)

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Package Leaflet

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