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ALFADEXX 2 MG/ML SOLUTION FOR INJECTION FOR HORSES, CATTLE, GOATS, PIGS, DOGS AND CATS

Authorised

- Dexamethasone sodium phosphate

Product identification

Medicine name:
ALFADEXX 2 MG/ML SOLUTION FOR INJECTION FOR HORSES, CATTLE, GOATS, PIGS, DOGS AND CATS

Active substance:
Dexamethasone sodium phosphate

Target species:
Cattle
Pig
Cat
Horse
Goat
Dog

Route of administration:
Intramuscular use
Subcutaneous use

Periarticular use
Intravenous use
Intraarticular 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:
Intramuscular use:

- **Cattle**
  - Milk. 72 hour
  - Meat and offal. 8 day
- **Pig**
  - Meat and offal. 2 day
- **Horse**
  - Milk. no withdrawal period

Not authorized for use in horses producing milk for human consumption.

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

Periarticular use:

- **Horse**
  - Milk. no withdrawal period

Not authorized for use in horses producing milk for human consumption.

  - Meat and offal. 8 day

Intravenous use:

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

- **Pig**
  - Meat and offal. 6 day

- **Horse**
  - Milk. no withdrawal period

Not authorized for use in horses producing milk for human consumption.

  - Meat and offal. 8 day

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

Intraarticular use:

- **Horse**
  - Milk. no withdrawal period

Not authorized for use in horses producing milk for human consumption.

  - 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:
Belgium

Available in:
Belgium

Package description:
Available only in French
Available only in French

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:
Alfasan Nederland B.V.

Marketing authorisation date:
11/01/2022

Manufacturing sites for batch release:
Produlab Pharma B.V.
Alfasan Nederland B.V.

Responsible authority:
Federal Agency For Medicines And Health Products

Authorisation number:
BE-V594373

Date of authorisation status change:
11/01/2022

Reference member state:
France

Procedure number:
FR/V/0430/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden

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

Documents

Package Leaflet

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

Summary of Product Characteristics

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

Labelling

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

Combined File of all Documents

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