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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:
Italy

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:
19/01/2023

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

Responsible authority:
Ministry Of Health

Authorisation number:
105549

Date of authorisation status change:
19/01/2023

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

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Documents

Combined File of all Documents

English (PDF)
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