Vitamin AD3E pro injectione, solution for injection for horses, cattle, pigs, and dogs

Authorised

- DL-ALPHA TOCOPHEROL ACETATE
- COLECALCIFEROL CONCENTRATE (OILY FORM)
- Retinol palmitate

Product identification

Medicine name:
Vitamin AD3E pro injectione, solution for injection for horses, cattle, pigs, and dogs
Belavit AD3E vet - Injeksjonsvæske, oppløsning - 176,47 mg/ml/50 mg/ml100 mg/ml

Active substance:
DL-ALPHA TOCOPHEROL ACETATE

COLECALCIFEROL CONCENTRATE (OILY FORM)

Retinol palmitate

Target species:
Cattle
Dog
Horse
Pig

Route of administration:
Subcutaneous use
Intramuscular use

Product details

Active substance and strength:

DL-ALPHA TOCOPHEROL ACETATE
50.00 milligram(s) / 1.00 millilitre(s)

COLECALCIFEROL CONCENTRATE (OILY FORM)
100.00 milligram(s) / 1.00 millilitre(s)

Retinol palmitate
176.46 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Subcutaneous use:

- **Cattle**
  - Milk. 120 hour
  - Meat and offal. 259 day
- **Dog**
- **Horse**
  - Meat and offal. 250 day
  - Milk. no withdrawal period

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

- **Pig**
  - Meat and offal. 194 day

Intramuscular use:

- **Cattle**
  - Milk. 120 hour
  - Meat and offal. 259 day
- **Dog**
- **Horse**
  - Meat and offal. 250 day

- Milk. no withdrawal period

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

- **Pig**
  - Meat and offal. 194 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QA11JA

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Norway

Package description:
(ID3): 1 unspecified outer container with 12 Bottle (Glass) with 100 millilitre(s) (1200 millilitre(s))
(ID2): 1 unspecified outer container with 6 Bottle (Glass) with 100 millilitre(s) (600 millilitre(s))
(ID1): 1 unspecified outer container with 1 Bottle (Glass) with 100 millilitre(s) (100 millilitre(s))

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:
Bela-Pharm GmbH & Co. KG

Marketing authorisation date:

21/05/2019

Manufacturing sites for batch release:
Bela-Pharm GmbH & Co. KG

Responsible authority:
Norwegian Medical Products Agency

Authorisation number:
18-12639

Date of authorisation status change:
21/05/2019

Reference member state:
Germany

Procedure number:
DE/V/0313/001

Concerned member states:
Austria Croatia Cyprus France Greece Iceland Ireland Italy Latvia Norway Portugal Slovenia Spain United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents