OXTRA DD 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats

Authorised

- Oxytetracycline hydrochloride

Product identification

Medicine name:
OXTRA DD 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats
Oxtra DD 100 mg/ml injektionsvæske, opløsning

Active substance:
Oxytetracycline hydrochloride

Target species:
Cattle
Dog
Sheep
Horse
Cat
Pig

Route of administration:
Intramuscular use
Intravenous use
Subcutaneous use

Product details

Active substance and strength:
Oxytetracycline hydrochloride
107.93 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. 35 day 24 hour dosage regimen
  - Meat and offal. 35 day Prolonged action dosage regimen
  - Milk. 72 hour 24 hour dosage regimen
- **Dog**
- **Sheep**
  - Meat and offal. 53 day 24 hour dosage regimen
  - Meat and offal. 18 day Prolonged action dosage regimen
  - Milk. 120 hour 24 hour dosage regimen
- **Horse**
  - Meat and offal. 6 month 24 hour dosage regimen
- **Cat**

- **Pig**
  - Meat and offal. 14 day 24 hour dosage regimen
  - Meat and offal. 13 day Prolonged action dosage regimen

Intravenous use:

- **Cattle**
  - Meat and offal. 35 day 24 hour dosage regimen
  - Milk. 72 hour 24 hour dosage regimen
- **Sheep**
  - Meat and offal. 53 day 24 hour dosage regimen
  - Milk. 120 hour 24 hour dosage regimen
- **Horse**
  - Meat and offal. 6 month 24 hour dosage regimen
- **Pig**
  - Meat and offal. 14 day 24 hour dosage regimen

Subcutaneous use:

- **Dog**
- **Cat**

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01AA06

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

Authorisation status:
Valid

Authorised in:
Denmark

Package description:
20 ml amber type II glass vial closed with chlorobutyl rubber stopper type I and sealed with an aluminium collar with a tamper-evident polypropylene seal, in a cardboard box.Pack-size:1 x 20 ml glass vial
50 ml amber type II glass vial closed with chlorobutyl rubber stopper type I and sealed with an aluminium collar with a tamper-evident polypropylene seal, in a cardboard box.Pack-size:1 x 50 ml glass vial
100 ml amber type II glass vial, closed with chlorobutyl rubber stopper type I and sealed with an aluminium collar with a tamper-evident polypropylene seal, in a cardboard box.Pack-size:1 x 100 ml glass vial
250 ml amber type II glass vial ,closed with chlorobutyl rubber stopper type I and sealed with an aluminium collar with a tamper-evident polypropylene seal, in a cardboard box.Pack-size:1 x 250 ml glass vial
100 ml amber type II glass vials, closed with chlorobutyl rubber stopper type I and sealed with an aluminium collar with a tamper-evident polypropylene seal, in a cardboard box.Pack-size:10 x 100 ml glass vial
100 ml amber PET vial, closed with chlorobutyl rubber stopper type I and sealed with an aluminium collar with a tamper-evident polypropylene seal, in a cardboard box.Pack-size:1 x 100 ml PET vial
250 ml amber PET vial, closed with chlorobutyl rubber stopper type I and sealed with an aluminium collar with a tamper-evident polypropylene seal, in a cardboard box.Pack-size:1 x 250 ml PET vial
100 ml amber PET vials, closed with chlorobutyl rubber stopper type I and sealed with an aluminium collar with a tamper-evident polypropylene seal, in a cardboard box.Pack-size:10 x 100 ml PET vial

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:
Fatro S.p.A.

Marketing authorisation date:
21/07/2020

Manufacturing sites for batch release:
Fatro S.p.A.

Responsible authority:
Danish Medicines Agency

Authorisation number:
62786

Date of authorisation status change:
21/07/2020

Reference member state:
Ireland

Procedure number:
IE/V/0521/001

Concerned member states:
Austria Belgium Denmark Germany Greece Italy Netherlands Poland Portugal Spain 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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