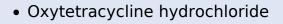
# OXTRA DD 100 mg/ml solution for injection for cattle, sheep, pigs, horses, dogs and cats

Authorised



# 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:		
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

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- 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

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- Meat and offal. 6 month 24 hour dosage regimen

# Pig

- Meat and offal. 14 day 24 hour dosage regimen

#### Subcutaneous use:

Dog

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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) Published on: 3/05/2024 Download

Source URL: https://medicines.health.europa.eu/veterinary/60000050213