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Oxytobel 10 IU/ml Solution for Injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats

Authorised

- Oxytocin

Product identification

Medicine name:
Oxytobel 10 IU/ml Solution for Injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats

Active substance:
Oxytocin

Target species:
Cattle
Dog
Goat
Sheep
Horse
Cat
Pig

Route of administration:
Intramuscular use
Intravenous use
Subcutaneous use

Product details

Active substance and strength:
Oxytocin
10.00 international unit(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. 0 day
  - Milk. 0 hour
- **Goat**
  - Meat and offal. 0 day
  - Milk. 0 hour
- **Sheep**
  - Meat and offal. 0 day
  - Milk. 0 hour
- **Horse**
  - Meat and offal. 0 day
  - Milk. 0 hour
- **Pig**
  - Meat and offal. 0 day

Intravenous use:

- **Cattle**
  - Meat and offal. 0 day
  - Milk. 0 hour
- **Goat**
  - Meat and offal. 0 day
  - Milk. 0 hour
- **Sheep**
  - Meat and offal. 0 day
  - Milk. 0 hour
- **Horse**
  - Meat and offal. 0 day
  - Milk. 0 hour
- **Pig**
  - Meat and offal. 0 day

Subcutaneous use:

- **Cattle**
  - Meat and offal. 0 day
  - Milk. 0 hour
- **Goat**
  - Meat and offal. 0 day
  - Milk. 0 hour
-

Sheep

- Meat and offal. 0 day
- Milk. 0 hour

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Horse

- Meat and offal. 0 day
- Milk. 0 hour

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Pig

- Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QH01BB02

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

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Authorisation status:
Valid

Authorised in:
United Kingdom (Northern Ireland)

Available in:
United Kingdom (Northern Ireland)

Package description:
Type II (100 ml) brown glass vials closed with bromobutyl rubber stopper and sealed with aluminium caps.6 x (1 x 100 ml) wrapped with clear foil (multipack)
Type II (100 ml) brown glass vials closed with bromobutyl rubber stopper and sealed with aluminium caps.12 x 100 ml in a cardboard box
Type II (100 ml) brown glass vial closed with bromobutyl rubber stopper and sealed with aluminium cap.1 x 100 ml in a cardboard box
Type II (50 ml) brown glass vials closed with bromobutyl rubber stopper and sealed with aluminium caps.6 x (1 x 50 ml) wrapped with clear foil (multipack)

Type II (50 ml) brown glass vials closed with bromobutyl rubber stopper and sealed with aluminium caps.12 x 50 ml in a cardboard box
Type II (50 ml) brown glass vial closed with bromobutyl rubber stopper and sealed with aluminium cap.1 x 50 ml in a cardboard box
Type I (25 ml) brown glass vials closed with bromobutyl rubber stopper and sealed with aluminium caps.10 x 25 ml in a cardboard box
Type I (25 ml) brown glass vial closed with bromobutyl rubber stopper and sealed with aluminium cap.1 x 25 ml in a cardboard box
Type I (10 ml) brown glass vials closed with bromobutyl rubber stopper and sealed with aluminium caps.12 x 10 ml in a cardboard box
Type I (10 ml) brown glass vials closed with bromobutyl rubber stopper and sealed with aluminium caps.5 x 10 ml in a cardboard box
Type I (10 ml) brown glass vial closed with bromobutyl rubber stopper and sealed with aluminium cap.1 x 10 ml in a cardboard box

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:
6/08/2014

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

Responsible authority:
The Veterinary Medicines Directorate

Authorisation number:
Vm 41816/4000

Date of authorisation status change:
16/06/2023

Reference member state:
Ireland

Procedure number:
IE/V/0313/001

Concerned member states:
Croatia Czechia Denmark Estonia France Hungary Iceland Norway Poland Slovakia United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

Combined File of all Documents