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
Oxytobel 10 IU/ml Roztwór do wstrzykiwań

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

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QH01BB02

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

Authorisation status:
Valid

Authorised in:
Poland

Package description:
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
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 vials closed with bromobutyl rubber stopper and sealed with aluminium caps.12 x 10 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 (25 ml) brown glass vials closed with bromobutyl rubber stopper and sealed with aluminium caps.10 x 25 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 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 vials closed with bromobutyl rubber stopper and sealed with aluminium caps.6 x (1 x 50 ml) wrapped with clear foil (multipack)
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 (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 vials closed with bromobutyl rubber stopper and sealed with aluminium caps.6 x (1 x 100 ml) wrapped with clear foil (multipack)

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:
21/09/2016

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

Responsible authority:
Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

Authorisation number:
2564

Date of authorisation status change:
21/09/2016

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

English (PDF)
Published on: 3/05/2024
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Package Leaflet

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Labelling

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