

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 i.j./mL, otopina za injekciju, za konje, goveda, svinje, ovce, koze, pse i mačke

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:

Croatia

Available in:

Croatia

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:

20/02/2019

Manufacturing sites for batch release:

Bela-Pharm GmbH & Co. KG

Responsible authority:

Ministry Of Agriculture Veterinary And Food Safety Directorate

Authorisation number:

UP/I-322-05/19-01/63

Date of authorisation status change:

20/02/2019

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)

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