

# 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

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### **Active substance:**

Oxytocin

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### **Target species:**

Cattle

Dog

Goat

Sheep

Horse

Cat

Pig

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### **Route of administration:**

Intramuscular use

Intravenous use  
Subcutaneous use

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## Product details

**Active substance and strength:**

Oxytocin  
10.00 international unit(s) / 1.00 millilitre(s)

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**Pharmaceutical form:**

Solution for injection

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**Withdrawal period by route of administration:****Intramuscular use:**

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**Cattle**

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

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**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

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#### **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

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### **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

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## **Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QH01BB02

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### **Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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### **Authorisation status:**

Valid

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### **Authorised in:**

Croatia

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### **Available in:**

Croatia

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### **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)

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Generic application (Article 13(1) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Bela-Pharm GmbH & Co. KG

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**Marketing authorisation date:**

20/02/2019

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**Manufacturing sites for batch release:**

Bela-Pharm GmbH & Co. KG

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**Responsible authority:**

Ministry Of Agriculture Veterinary And Food Safety Directorate

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**Authorisation number:**

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

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**Date of authorisation status change:**

20/02/2019

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**Reference member state:**

Ireland

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**Procedure number:**

IE/V/0313/001

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**Concerned member states:**

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

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

Summary of Product Characteristics

English (PDF)

Published on: 3/05/2024

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