1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytobel 10 IU/ml solution for injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Oxytocin 16.6 µg
(equivalent to 10 IU Oxytocin)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorobutanol hemihydrate	3.0 mg
Acetic Acid, Glacial	
Ethanol 96 %	
Water for Injections	

Clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses (mares), cattle (cows), pigs (sows), sheep (ewes), goats (nanny), dogs (bitches) and cats (queens).

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for:

- Obstetric use (stimulation of uterine contraction to facilitate parturition in the presence of a fully dilated cervix, promotion of involution of the post partum uterus, aid in the control of post partum haemorrhage).
- Promotion of milk let-down in cases of agalactia.

3.3 Contraindications

Do not use in cases of obstructive dystocia and/or in cases of non-dilatation of the uterine cervix.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

Adrenaline at physiological levels markedly reduces the effect of oxytocin on the uterus or mammary gland. For this reason the animal should not be frightened when complete oxytocin effect is desired to cause either milk "let-down" or uterine contractions.

3.5 Special precautions for use

Special precautions for safe use in target species:
When the veterinary medicinal product is used as an aid in parturition cervical dilation must be confirmed prior to administration to prevent risk of foetal death and possible uterine rupture.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Pregnant or lactating women should avoid handling the veterinary medicinal product as it could cause smooth muscle (e.g. uterine) contraction.
When administering the veterinary medicinal product, care should be taken to avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

None.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during parturition and lactation. Do not use during pregnancy except at the time of parturition.

3.8 Interaction with other medicinal products and other forms of interaction

This veterinary medicinal product may be used concurrently with antibiotics in the treatment of endometritis.
Stimulation of β-adrenergic receptors may reduce oxytocin's effects on the uterus and mammary gland.
If sympathomimetic agents or other vasoconstrictors are used concurrently with oxytocin, post-partum hypertension may result.

3.9 Administration routes and dosage

Intravenous, subcutaneous or intramuscular use.

Doses when administered by subcutaneous or intramuscular injection:

Mares & Cows	4 – 6 ml
Sows	1 – 3 ml
Ewes & Nanny goats	1 – 2 ml
Bitches & Queens	0.25 – 1 ml

For treatment of agalactia the stated higher dosage level should be used.

The veterinary medicinal product may be administered by slow intravenous injection at dose rates one third of the above.

Enhanced dose rates will not result in proportionally increased pharmacological effects.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Excessive doses of the veterinary medicinal product may delay parturition by producing uncoordinated uterine contractions which interfere with the progress of the foetus especially in multiple pregnancies. Treatment of overdose is palliative and there are no specific antidotes.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: zero days.

Milk: zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QH01BB02

4.2 Pharmacodynamics

Oxytocin is a hormone of the posterior lobe of the hypophysis. It influences the rhythmic contraction of the oxytocin sensitive smooth muscle apparatus. Of special significance is the increase of strength and frequency of the uterine contractions at the beginning of labour.

In the lactating cow the myoepithelial cells, which cover the alveoli of the mammary glands, are contracted by the influence of oxytocin and the milk is passed into the milk ducts.

The veterinary medicinal product is a sterile, aqueous, protein-free injectable solution of synthetic oxytocin which corresponds chemically as well as pharmacologically with naturally occurring oxytocin.

4.3 Pharmacokinetics

Following injection, oxytocin has a rapid onset of activity as physiological effects are usually detected within minutes following administration. Oxytocin is cleared very fast, as its mean half life of distribution is about 2 minutes while its half life of elimination is around 12 minutes.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after first opening the immediate packaging: 7 days.

5.3 Special precautions for storage

Keep the container in the outer carton in order to protect from light.
Store in a refrigerator (2 °C – 8 °C).
Once opened do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Type I (10 ml, 25 ml) or type II (50 ml, 100 ml) brown glass vials closed with bromobutyl rubber stopper and sealed with aluminium caps.

1 x 10 ml in a cardboard box
5 x 10 ml in a cardboard box
12 x 10 ml in a cardboard box
1 x 25 ml in a cardboard box
10 x 25 ml in a cardboard box
1 x 50 ml in a cardboard box
12 x 50 ml in a cardboard box
6 x (1 x 50 ml) wrapped with clear foil (multipack)
1 x 100 ml in a cardboard box
12 x 100 ml in a cardboard box
6 x (1 x 100 ml) wrapped with clear foil (multipack)

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co. KG

7. MARKETING AUTHORISATION NUMBER(S)

VPA10445/001/001

8. DATE OF FIRST AUTHORISATION

21/02/2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

23/01/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).