Summary of Product Characteristics

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

1 ml contains:

Active substance:

Oxytocin	16.6	µg
(equivalent to 10 IU Oxytocin)		

Excipients:

Chlorobutanol hemihydrate	3.0	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

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

4.2 Indications for use, specifying the target species

In the mare, cow, sow, ewe, nanny, bitch and queen the 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.

4.3 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 substance or to any of the excipients.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
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 product as it could cause smooth muscle (e.g. uterine) contraction.
When administering the 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.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

The product is indicated for use, as appropriate, during parturition and lactation. Do not use during pregnancy except at the time of parturition.

4.8 Interaction with other medicinal products and other forms of interactions

This veterinary medicinal product maybe 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.

4.9 Amounts to be administered and administration route

Administered by subcutaneous or intramuscular injection.

Mare & Cow 4 – 6 ml
Sow 1 – 3 ml
Ewe & Nanny 1 – 2 ml
Bitch & Queen 0.25 – 1 ml
For treatment of agalactia the stated higher dosage level should be used.
The 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Meat and offal: zero days.
Milk: zero hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Systemic hormonal preparations; Posterior pituitary lobe hormones; Oxytocin.
ATCvet code: QH01BB02

5.1 Pharmacodynamic properties

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 milkducts.
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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorobutanol Hemihydrate
Acetic Acid, Glacial
Ethanol 96 %
Water for Injections

6.2 Major incompatibilities

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

6.3 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

6.4 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.

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co. KG
Lohner Straße 19
D-49377 Vechta
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10445/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 February 2014
Date of last renewal: 25 January 2019

10 DATE OF REVISION OF THE TEXT

January 2019