

Oxytobel

10 IU/ml Solution for Injection

Actives per 1ml:

Oxytocin 16.6 µg (equivalent to 10 IU Oxytocin)

INDICATIONS

Oxytobel is licensed for use in horses, cattle, pigs, sheep, goats, dogs and cats.

In the mare, cow, sow, ewe, goat, bitch and cat 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.

BENEFITS

- Multi-species use
- Zero milk withdrawal
- Zero meat withdrawal
- Licensed for IV, IM and SC use
- Suitable for promotion of milk let down
- Stimulates uterine contraction
- Promotes uterine involution



LIST NO.	UNIT	CASE
10XY043	50ml	12



See reverse side for Administration and Dosage.

Oxytobel

10 IU/ml Solution for Injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats

PRESENTATION

Solution for injection.
Clear colourless solution.

USES

Promote milk let-down
Aid parturition
Stimulates uterine contraction
Promote the involution of the uterus
Aid in the control of post-partum haemorrhage).

DOSAGE AND ADMINISTRATION

Administered by subcutaneous or intramuscular injection.

Mare & Cow	4 – 6 ml
Sow	1 – 3 ml
Ewe & Goat	1 – 2 ml
Bitch & Cat	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

CONTRA-INDICATIONS & WARNINGS

Adrenaline at physiological levels markedly reduces the effect of Oxytocin so the animal should not be frightened when complete Oxytocin effect is desired to cause either milk "let-down" or uterine contractions.

Cervical dilation must be confirmed prior to administration to aid parturition to prevent risk of foetal death and possible uterine rupture.

Pregnant or lactating women should avoid handling the product as it could cause smooth muscle (e.g. uterine) contraction.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Oxytobel should not be used in the pre-partum pregnant animal.

WITHDRAWAL PERIODS

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

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.

Oxytobel 10 IU/ml is a sterile, aqueous, protein-free injectable solution of synthetic oxytocin which corresponds chemically as well as pharmacologically with naturally occurring oxytocin.

PHARMACOKINETIC PARTICULARS

Following injection, oxytocin has a rapid onset of activity. Its mean half-life of distribution is about 2 minutes while its half-life of elimination is around 12 minutes.

LIST OF EXCIPIENTS

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

STORAGE

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months
Shelf-life after first opening the immediate packaging: 7 days
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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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.

Not all pack sizes may be marketed. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

MARKETING AUTHORISATION HOLDER:

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

MARKETING AUTHORISATION NUMBER:

Vm: 41816/4000

LEGAL CATEGORY:

POM-V

DISTRIBUTED BY:

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Unit 2, Bryn Cefni Industrial Park
Llangefni, Anglesey,
Wales LL77 7XA UK
Use Medicines Responsibly
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