OXATOBEL 10 IU/ML SOLUTION FOR INJECTION FOR HORSES, CATTLE, SHEEP, PIGS, GOATS, DOGS AND CATS Oxytocin 10IU/ml

DATA SHEET



INDICATIONS:

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 postpartum uterus, aid in the control of post-partum haemorrhage).

• Promotion of milk let-down in cases of agalactia.

LIST No UNIT PACKAGE CASE SIZE 10XY044 25 ml 10

See reverse for Administration & Dosage

BENEFITS

- Multi-species use
- Zero milk withdrawal
- Zero meat withdrawal
- For IV, IM and SC use



Oxytobel

10 IU/ml solution for injection for horses, cattle, sheep, pigs, goats, dogs and cats

10 IU/ml Solution for Injection

PRESENTATION

Clear, colourless solution for injection containing 16.9µg/ml oxytocin (equivalent to 10 IU oxytocin/ml).

INDICATIONS FOR USE

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

Promotion of milk let-down in cases of agalactia. Stimulation of uterine contraction in the presence of fully dilated cervix to aid parturition. Promotion of involution of the uterus.

To aid in the control of post-partum haemorrhage.

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.

SPECIAL WARNINGS FOR 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.

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 PRODUCT

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.

ADVERSE REACTIONS None.

USE DURING PREGNANCY AND LACTATION

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

INTERACTIONS

This veterinary medicinal product maybe used concurrently with antibiotics in the treatment of endometritis.



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Global Excellence in Animal Health

Stimulation of $\beta\text{-adrenergic}$ 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.

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
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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.

OVERDOSE

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.

WITHDRAWAL PERIODS

Meat and offal: zero days Milk: zero hours

PHARMACODYNAMIC PROPERTIES

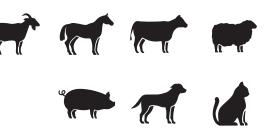
Oxytocin is a hormone of the posterior lobe of the hypophysis. It influences the rhythmic contraction of the oxytocin sensitive smooth muscle apparatus. Of special significance is the increase of strength and frequency of the uterine contractions at the beginning of labour. In the lactating cow the myoepithelial cells, which cover the alveoli of the mammary glands, are contracted by the influence of oxytocin and the milk is passed into the 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.

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

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of distribution is about 2 minutes while its half-life of elimination is around 12 minutes.

EXCIPIENTS

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

MAJOR INCOMPATIBILITIES

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

SHELF LIFE

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.

DISPOSAL

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

LEGAL CATEGORY

POM-V

MARKETING AUTHORISATION NUMBER Vm 41816/4000

MARKETED IN THE UK BY

Bimeda UK Unit 2, Bryn Cefni Industrial Park Llangefni, Anglesey, Wales, LL77 7XA 01248 725400

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