# **OXYTOBEL**

Oxytocin 10 IU/ml Solution for Injection

### 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.

#### **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 when fully dilated cervix
- Promotes uterine involution

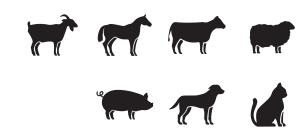


See reverse for Administration & Dosage



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#### **PRESENTATION**

Solution for injection. Clear colourless solution.

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#### DOSAGE AND ADMINISTRATION

Administered by subcutaneous or intramuscular injection.

Mare & Cow	4-6 ml
Sow	1-3 ml
Ewe & nanny	1-2 ml
Ritch and Oueen	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.

#### **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 partiturition 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.

#### **OVERDOSE**

Excessive doses of the veterinary medicinal product may delay parturition by producing uncoordinated uterine contraction which interfere with the progress of the fetus especially in multiple pregnancies.

Treatment of overdose is palliative and ther 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 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.

#### **USE DURING PREGNANCY OR LACTATION**

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

#### INTERACTION WITH OTHER MEDICINAL PRODUCTS

May be used concurrently with antibiotics in the treatment of endometritis,

Stimulation of  $\beta$ -adrenergic receptors may reduce oxytocin's effects on the uterus and mammary pland.

If sympathomimetic agents or other vasoconstrictors are used concurrently with oxytocin, post-partum hypertension may result.

#### MAJOR INCOMPATIBILITIES

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

#### 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.

#### MARKETING AUTHORISATION NUMBER

VPA 10445/001/001

#### **LEGAL CATEGORY**

POM

#### DISTRIBUTED BY

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