1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytobel 10 IU/ml solution for injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats
Vetocin 10 IU/ml solution for injection for Horses, Cattle, Pigs, Sheep, Goats, Dogs and Cats (NO)

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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytobel 10 IU/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Oxytocin 10 IU/ml

3. PACKAGE SIZE

10 ml
5 x 10 ml
12 x 10 ml
25 ml
10 x 25 ml
50 ml
12 x 50 ml
100 ml
12 x 100 ml

4. TARGET SPECIES

Horses, cattle, pigs, sheep, goats, dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

i.v. i.m. s.c.

7. WITHDRAWAL PERIODS

Withdrawal periods:

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use by: _____
Once opened, use within 7 days.

9. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton in order to protect from light.
Store in a refrigerator.

Once opened do not store above 25 °C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co. KG

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Bottle 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytobel 10 IU/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Oxytocin 10 IU/ml

3. TARGET SPECIES

Horses, cattle, pigs, sheep, goats, dogs and cats.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
i.v. i.m. s.c.

5. WITHDRAWAL PERIODS

Withdrawal periods:

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

6. EXPIRY DATE

Exp. {mm/yyyy}
Once openend, use within 7 days.
Once opened, use by: _____

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co. KG

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Bottle 10 ml, 25 ml, 50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Oxytocin 10 IU/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use by: _____

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

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

Excipients:
Chlorobutanol hemihydrate 3.0 mg

Clear colourless solution.

3. Target species

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

4. Indications for use

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.

5. 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.

6. Special warnings

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.

Special precautions for safe use in the 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.

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

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.

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.

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

7. Adverse events

None.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Intravenous (**i.v.),** Intramuscular **(i.m.),** Subcutaneous (**s.c.)** use.

Doses when administered by subcutaneous or intramuscular injection:

Mare & Cow	4 – 6 ml
Sow	1 – 3 ml
Ewe & 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.

9. Advice on correct administration

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of the month.

Shelf-life after first opening the immediate packaging: 7 days.

12. Special precautions for the disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:

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.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder, manufacturer responsible for batch release:
Bela-Pharm GmbH & Co. KG
Lohner Str. 19
49377 Vechta
+49 4441 873 555
Germany

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.