Oxytocin 10 I.E./ml

16.6 µg, solution for injection

Active ingredient: Oxytocin

Target species: horses, cattle, sheep, goats, pigs, dogs and cats.

Name and address of the marketing authorisation holder:
bela-pharm GmbH & Co. KG, Lohner Str. 19, 49377 Vechta - Germany

Statement of the active substance(s) and other ingredient(s):
1.0 ml solution contains:
Pharmacological active substance:
Oxytocin 16.6 µg
(corresponds to 10 I.U. oxytocin)
Adjuvants:
Chlorbutanol hemihydrate 3.0 mg

Indications:
Horse, *cattle*, *sheep*, *goat*, *pig*, *dog*, *cat*.
For stimulation of uterine contractions during parturition and in the early puerperium, uterine inertia.

Horse: Induction of parturition, retentio secundinarum caused by uterine inertia, disturbances of milk secretion,
Cattle: Atonia uteri sub partu and post partum, retentio secundinarum caused by uterine inertia, supportive therapy of endometritis in early puerperium, disturbances of milk secretion, milk ejection of residual milk for support of mastitis therapy.
Sheep: for supportive therapy of endometritis in the early puerperium
Goat: to support uterine contraction following caesarean section.
Pig: Atonia uteri sub partu and post partum, retentio secundinarum caused by uterine inertia, shortening of the duration of birth, disturbances of milk secretion, milk ejection of residual milk for support of mastitis therapy.
Dog: for supportive therapy of endometritis in the early puerperium, disturbances of milk secretion.
Cat: disturbances of milk secretion.

Contraindications:
Do not use in:
- *mares* unprepared for birth.
- acceleration of birth in animals with insufficient opening of the cervix.
- mechanical birth obstacles, unfavourable foetal positions, convulsive labour, imminent uterine rupture, torsio uteri, significant cephalopelvic disproportion, malformation of the birth canal.
- animals hypersensitive to oxytocin.

Adverse reactions (frequency and seriousness):
- Uterine hypercontractility.
- Uterine rupture (especially in carnivores).
- Hypercontractility of the uterus with a decrease of blood supply by the umbilical cord, foetal hypoxia and a reduction of viability of the foetus.

- in *pigs* at doses of 5-10 I.U. oxytocin/animal i.m. in connection with prostaglandins for birth induction: tetanus uteri, prolonged partum, and premature detachment of the placenta.
- in *piglets* following treatment of milk retention of the *sow* with 22 I.U. of oxytocin per 100 kg b.w. / day: incidence of piglet diarrhoea for one day.

Target species:
Horse, *cattle*, *sheep*, *goat*, *pig*, *dog*, *cat*.

Dosage for each species, route(s) and method of administration:
For intravenous, intramuscular and subcutaneous injection, for intravenous drop infusion and intramuscular infusion.

For single administration, if necessary for repeated administration.
10 I.U. oxytocin correspond to 1 ml Oxytocin 10 I.E./ml.

Cattle:
Disturbances of milk secretion, milk ejection of residual milk for support of mastitis therapy:
0.5 - 10 I.U. oxytocin/animal intravenously
20 - 40 I.E. oxytocin/animal intramuscularly or subcutaneously

Promotion of uterine contractions during parturition and in early puerperium, uterine inertia:
5 - 10 I.U. oxytocin/animal intravenously
1 - 20 I.U. oxytocin/animal intramuscularly

Atonia uteri sub partu and post partum, retentio secundinarum caused by uterine inertia, supportive therapy of endometritis in early puerperium:
25 I.U. oxytocin/animal intravenously

Sheep:
Promotion of uterine contractions during parturition and in early puerperium, uterine inertia:
5 - 10 I.U. oxytocin/animal intravenously
1 - 20 I.U. oxytocin/animal intramuscularly

Supportive therapy of endometritis in early puerperium:
5 - 10 I.U. oxytocin/animal intravenously.

Goat:
Promotion of uterine contractions during parturition and in early puerperium, uterine inertia:
1 - 3 I.U. oxytocin/animal intramuscularly, subcutaneously.

Support of uterine contraction following caesarean section:
5 I.U. oxytocin/animal intravenously, intramuscularly.

Horse:
Induction of birth, promotion of uterine contractions during parturition and in early puerperium, uterine inertia:
10 I.U. oxytocin/animal intravenously
40 I.U. oxytocin/animal intramuscularly

Retentio secundinarum caused by uterine inertia:
50 - 60 I.U. oxytocin/hour/animal in form of an intravenous drop infusion

Disturbances in milk release:
30 - 40 I.U. oxytocin/animal intramuscularly

Pig:
Promotion of uterine contractions during parturition and in early puerperium, uterine inertia, shortening of birth:
1 - 10 I.U. oxytocin/animal intravenously
20 - 25 I.U. oxytocin/animal intramuscularly
25 I.U. oxytocin/animal intramuscularly + 0.125 I.U. oxytocin/min/animal in form of an intramuscular infusion

Disturbances of milk secretion, milk ejection of residual milk for support of mastitis therapy:
1 - 10 I.U. oxytocin/animal intravenously
15 I.U. oxytocin/animal intramuscularly

Antonia uteri sub partu and post partum:
20 - 40 I.U. oxytocin/animal intramuscularly

Retentio secundinarum caused by uterine inertia:
0.5 I.E. oxytocin/ animal intramuscularly, repeated administration over several hours

Dog:
Promotion of uterine contractions during parturition and in early puerperium, uterine inertia:
0.15 - 1 I.U. oxytocin/animal intravenously, intramuscularly or subcutaneously

Supportive therapy of endometritis in early puerperium:
3 - 10 I.U. oxytocin/animal subcutaneously

Disturbances of milk secretion:
0.2 - 1 I.U. oxytocin/animal intravenously, intramuscularly or subcutaneously

Cat:
Promotion of uterine contractions during parturition and in early puerperium, uterine inertia:
0.3 - 1 I.U. oxytocin/animal intramuscularly or subcutaneously

0.1 - 0.2 I.U. oxytocin intramuscularly or subcutaneously and 10 - 20 mg of a pharma-ceutical with utero-spamolytic effect, repeat administration in intervals of 2 - 3 hours.

Disturbances of milk secretion:
0.1 - 0.25 I.U. oxytocin/animal intravenously, intramuscularly or subcutaneously

If oxytocin was given two times to the queen for treatment of uterine inertia without success, a caesarean section is recommended.

Advice on correct administration:
Special warnings for each target species:
Not indicated.
Special precautions for the use in animals:
Intravenous injection has to be done slowly.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The direct contact of the pharmaceutical with the skin or mucosa of the user is to be avoided. Avoid self-injection. Following accidental self-injection seek medical advice immediately. Pregnant women, especially in the last third of pregnancy shall avoid the contact with the product, as Oxytocin may provoke contractions of the smooth musculature (e.g. uterus).
Use during pregnancy, lactation or lay:
Not indicated.
Interaction with other medicinal products and other forms of interaction:
ß-adrenolytics increase the labour-promoting effects of oxytocin.
prostaglandins and oxytocin increase each other in the promotion of labour.
Overdose (symptoms, emergency procedures, antidotes):
Overdosage may cause:
- short-time vasodilation and decrease in blood pressure
- retention of water
- hypercontractility of the uterus with a decrease of blood supply by the umbilical cord, foetal hypoxia and a reduction of viability of the foetus.
- tachycardia
- uterine rupture
- in *horses* birth complications (strong labour pain and retentio secundinarum)
- in *pigs* delay of birth

In these cases stop injection of Oxytocin 10 I.E./ml immediately.
Incompatibilities:
Mixtures with other pharmaceuticals are to be avoided because of the danger of possible incompatibilities.

Withdrawal period(s):
Intravenous injection:

Horse, cattle, sheep, goat:	Edible tissues:	0 days
	Milk:	0 days
Pig:	Edible tissues:	0 days

Intramuscular or subcutaneous injection:

Horse, cattle, sheep, goat:	Edible tissues:	3 days
	Milk:	0 days
Pig:	Edible tissues:	3 days

Special storage precautions:
Store in a refrigerator (2 - 8 °C).
After opening store at temperatures not exceeding 25 °C.
Keep out of reach and sight of children.
Shelf life after first opening of the container: 7 days
Residuals of the pharmaceutical remaining in the container after the period to be used up is terminated are to be wasted.
Do not use after the expiration date stated on the label.

Special warnings:
None.

Special precautions for the disposal of unused product or waste materials:
Remaining quantities shall be preferably given to pollutant collecting points. When wasted together with the general household waste, it has to be ensured that no misuse of the pharmaceutical is possible. Veterinary pharmaceuticals must not be wasted with wastewater or sewage systems. Local regulations for the disposal of pharmaceuticals have to be observed.

Date on which the package leaflet was last approved: 17.01.2013

Marketing authorisation number: 6932755.00.00 (Germany)

For Veterinary use only.

Available on prescription only!