Oxytocin Vet





Injection solution for cattle, sheep, goats, horses, pigs, dogs, cats

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Veyx-Pharma GmbH Soehreweg 6 34639 Schwarzenborn Germany

NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytocin Vet, 10 IU/ml Injection solution for cattle, sheep, goats, horses, pigs, dogs, cats

STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS *Active substance:*

Oxytocin

Excipients: Chlorobutanol hemihydrate

16.6 µg/ml (equivalent to 10.0 IU/ml)

3.0 mg/ml

INDICATIONS

Cattle, Sheep, Goats, Horses, Pigs, Dogs, Cats:

To stimulate uterine contractions during parturition and the early stages of the puerperium, uterine inertia.

Cattle:

Atonia uteri sub partu and post partum, retentio secundinarum caused by uterine inertia, supporting the therapy for endometritis in the early puerperium, milk let-down disorders, expulsion of the residual milk in support of a mastitis therapy.

<u>Sheep:</u>

As a supportive therapy for endometritis during the early puerperium.

<u>Goats:</u>

In support of uterine contractions after sectio caesarea.

Horses:

Induction of parturition, retentio secundinarum caused by uterine inertia, milk let-down disorders.

<u>Pigs:</u>

Atonia uteri sub partu and post partum, retentio secundinarum caused by uterine inertia, shortening the duration of parturition, milk let-down disorders, expulsion of the residual milk in support of a mastitis therapy.

<u>Dogs:</u>

As a supportive therapy for endometritis in the early puerperium, milk let-down disorders.

<u>Cats:</u>

Milk let-down disorders.

CONTRAINDICATIONS

Use in the mare not ready for foaling, use to speed up parturition in case of an undilated cervix, mechanical hindrances to birth, malpositions, spasmodic contractions, risk of uterine rupture, torsio uteri, relative excessively large fetuses, malformed birth canal, hypersensitivity to Oxytocin.

ADVERSE REACTIONS

- Uterine hypercontractibility
- Uterine rupture (particularly in carnivores)
- Sustained contraction of the uterus with a blockage of the flow to the navel, foetal hypoxia resulting in a reduction in the survival viability of the foetuses
- in the pig at dosages of 5 10 IU Oxytocin/animal i.m. combined with prostaglandins for induction of parturition, prolonged contractions of the uterus, extended duration of parturition, premature placental detachment
- in suckling piglets following treatment for lack of milk retention in the sow at a dosage rate of 22 IU Oxytocin per 100 kg LW/day the occurrence of piglet diarrhoea (1 day)

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon or pharmacist.

TARGET SPECIES

Cattle, sheep, goats, horses, pigs, dogs, cats

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intravenous, intramuscular and subcutaneous injection.

For intravenous drip infusion and intramuscular infusion.

For a single application. For repeat treatments, as required.

10 IU Oxytocin equates to 1 ml "Oxytocin Vet injection solution".

<u>Cattle:</u>

Milk let-down disorders, expulsion of residual milk in support of a mastitis therapy: 0.5 - 10 IU Oxytocin/animal intravenous

20 - 40 IU Oxytocin/animal intramuscular or subcutaneous

Stimulating uterine contractions during parturition and the early puerperium, uterine inertia:

5 - 10 IU Oxytocin/animal intravenous

1 - 20 IU Oxytocin/animal intramuscular

Atonia uteri sub partu and post partum, retentio secundinarum caused by uterine inertia, as a supportive therapy for endometritis during the early puerperium: 25 IU Oxytocin/animal intravenous

<u>Sheep:</u>

Stimulating uterine contractions during parturition and the early puerperium, uterineinertia:

5 - 10 IU Oxytocin/animal intravenous

1 - 20 IU Oxytocin/animal intramuscular

As a supportive therapy for endometritis during the early puerperium:

5 - 10 IU Oxytocin/animal intramuscular

<u>Goats:</u>

Stimulating uterine contractions during parturition and the early puerperium, uterineinertia:

1 - 3 IU Oxytocin/animal intramuscular, subcutaneous

In support of uterine contractions following sectio caesarea:

5 IU Oxytocin/animal intravenous, intramuscular

Horses:

Induction of parturition, stimulating uterine contractions during parturition and the early puerperium, uterine inertia:

10 IU Oxytocin/animal intravenous

40 IU Oxytocin/animal intramuscular

Retentio secundinarum caused by uterine inertia:

50 – 60 IU Oxytocin/hour/animal as an intravenous continuous drip infusion

Milk let-down disorder:

30 - 40 IU Oxytocin/animal intramuscular

<u>Pigs:</u>

Stimulating uterine contractions during parturition and the early puerperium, uterine inertia, shortening the duration of parturition:

1 – 10 IU Oxytocin/animal intravenous

20 - 25 IU Oxytocin/animal intramuscular

25 IU Oxytocin/animal intramuscular + 0.125 IU Oxytocin/min/animal as an intramuscular infusion

Milk let-down disorder, expulsion of residual milk in support of a mastitis therapy: 1 – 10 IU Oxytocin/animal intravenous

15 IU Oxytocin/animal intramuscular

Atonia uteri sub partu and post partum:

20 - 40 IU Oxytocin/animal intramuscular

Retentio secundinarum caused by uterine inertia:

0.5 IU Oxytocin/animal intramuscular, repeat treatments over a number of hours <u>Dogs:</u>

Stimulating uterine contractions during parturition and the early puerperium, uterine inertia:

0.15 - 1.0 IU Oxytocin/animal intravenous, intramuscular or subcutaneous

As a supportive therapy for endometritis during the early puerperium:

3 - 10 IU Oxytocin/animal subcutaneous

Milk let-down disorder:

0.2 - 1.0 IU Oxytocin/animal intravenous, intramuscular or subcutaneous

Cats:

Stimulating uterine contractions during parturition and the early puerperium, uterine inertia:

0.3 - 1.0 IU Oxytocin/animal intramuscular or subcutaneous

0.1-0.2 IU Oxytocin intramuscular or subcutaneous and 10-20 mg of an active substance with an utero-spasmolytic effect, repeating the treatment at intervals of 2-3 hours

Milk let-down disorders:

0.1-0.25 IU Oxytocin/animal intravenous, intramuscular or subcutaneous In the cat, in case of a double treatment using an Oxytocin application being unsuccessful for the treatment of uterine inertia, then a sectio caesarea should be carried out.

ADVICE ON CORRECT ADMINISTRATION

Inject very slowly during intravenous injection.

WITHDRAWAL PERIODS

Intravenous injection	Meat and offal:	Zero days
Cattle, sheep, goats, horses:	Milk:	Zero days
Pigs:	Meat and offal:	Zero days
Intramuscular and subcutaned <u>Cattle, sheep, goats, horses:</u>	Meat and offal:	3 days Zero days

<u>Pigs:</u>

Milk: Meat and offal:

3 days

SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the label and the outer carton.

Store in a refrigerator (2 - 8 °C).

Protect from light in the outer carton.

Shelf-life after first opening the bottle: 28 days.

Following the expiry of this period the remainder of the drug in the container is to be disposed of.

SPECIAL WARNING(S)

<u>Special warnings for each target species:</u> Not applicable.

Special precautions for use:

Special precautions for use in animals:

Inject very slowly during intravenous injection.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Administration should be performed with caution in order to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately. Pregnant women should avoid handling the product, especially during the last 3 months of pregnancy as Oxytocin can induce contractions of the smooth musculature (e.g. the uterus).

<u>Use during pregnancy, lactation or lay:</u> Not applicable.

Interaction with other medicinal products and other forms of interaction:

 β -adrenolytics strengthen the contraction promoting effects of Oxytocin. Upon simultaneous administration of prostaglandins and Oxytocin, the labour-promoting effects are intensified reciprocally.

Overdose (symptoms, emergency procedures, antidotes), if necessary:

Overdosing can lead to temporary vasodilatation and a fall in blood pressure, water retention, prolonged sustained contraction of the uterus with a blockage of the flow through the navel, foetal hypoxia and a resulting reduction in the foetuses' survival chances, tachycardia, uterine rupture, foaling complications in the horse (violent contractions, retentio secundinarum), to the cessation of farrowing in the pig.

The treatment with Oxytocin injection solution should immediately cease in, these cases.

Incompatibilities: Not applicable.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

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

To be supplied only on veterinary prescription.

OTHER INFORMATION

50 ml vial

Not all package sizes may be marketed.