1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytocin Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Oxytocin (synthetic) 10 I.U.

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 (preservative)	4.75 mg
Glacial acetic Acid	
Sodium Acetate trihydrate	
Sodium chloride	
Water for injections	

A clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

Uterine inertia, retention of the placenta, agalactia, prevention of haemorrhages after caesarean section or after hard delivery.

3.3 Contraindications

Do not use in cases of incomplete dilation of the cervix or any form of obstructive dystocia.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

When oxytocin is used as an aid to parturition, cervical dilation must be confirmed prior to administration to prevent the risk of foetal death and possible uterine rupture.
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 “letdown” or uterine contractions.

3.5 Special precautions for use

Special precautions for safe use in the target species:
If uterine hyperactivity occurs, oxytocin administration should be discontinued immediately. Oxytocin should not be given simultaneously by more than one route of administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Hypersensitivity reactions may rarely occur; avoid skin contact with the solution.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

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

Undetermined frequency (cannot be estimated from the available data):	Hypersensitivity reaction

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:
Do not use during pregnancy. Only when the animal is full term should the product be administered.

3.8 Interaction with other medicinal products and other forms of interaction

Severe hypertension has been reported in humans when oxytocin was given 3-4 hours following prophylactic administration of a vasoconstrictor in conjunction with caudal block anaesthesia. Reports of interactions in the veterinary science are lacking.

3.9 Administration routes and dosage

For intramuscular or intravenous use.
Obstetrics:
Mare: 20-50 IU per animal by intramuscular injection.
40-50 IU per animal by slow intravenous infusion (over 1 hr).
Cow: 20-50 IU per animal by intramuscular injection.
Ewe: 5-30 IU per animal by intramuscular injection.
Goat: 5-15 IU per animal by intramuscular injection.
Sow: 10-40 IU per animal by intramuscular injection.
Bitch: 0.5-3 IU per animal depending on bodyweight by intramuscular injection (administration during delivery).
0.3-2 IU intravenous or 1-10 IU by intramuscular injection (administration post partum).
Queen: 0.3-1 IU per animal depending on bodyweight by intramuscular injection (administration during delivery).
0.15-1 IU intravenous or 1-3 IU by intramuscular injection (administration post partum).

During or shortly after delivery the minimum dose should be administered in all large animal species; this dosage can be repeated after approximately 30 minutes. The maximum dosage should be administered when several hours have passed since delivery.

Milk letdown:
Cow and mare: 10-40 IU
Ewe, goat and sow: 5-20 IU
Bitch and queen: 1-10 IU

To ensure a correct dosage, body weight should be determined as accurately as possible.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

When oxytocin is administered in excessive dosage, hyperstimulation of the uterus, with strong (hypertonic) and/or prolonged (tetanic) contractions, or an increased uterine tone between the contractions may occur, possibly resulting in uterine rupture, cervical and vaginal lacerations, postpartum haemorrhage, placental separation, impaired uterine blood flow, amniotic fluid embolism, and foetal trauma including intracranial haemorrhage.
Excessive doses of oxytocin may delay parturition by producing uncoordinated uterine contractions which interfere with the progress of the foetus especially in multiple pregnancies.

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 naturally occurring hormone present in the female and male organism of all mammalian species. Its chemical structure is a nonapeptide.
Oxytocin causes marked contraction of smooth muscle, in particular the uterus and the myoepithelial cells surrounding the milk secreting alveolus of the mammary gland. Functionally, oxytocin has a role in parturition and milk ejection. Oxytocin changes the weak spontaneous and irregular contractions of the oestrogen stimulated uterus into regular forceful and purposeful contractions. On the lactating mammary gland oxytocin provokes contractions of the myoepithelial tissue thus causing milk-ejection and at suckling stimulus milk let-down. Shortly before, during and shortly after birth susceptibility to the effects of oxytocin is distinct, but this susceptibility declines in time, and 24 hours after delivery dosages should be significantly increased.

4.3 Pharmacokinetics

The distribution and fate of oxytocin in the body following injection is characterized by a fast absorption and a short half-life in plasma and a rapid removal from plasma by kidney and liver. The lactating mammary gland inactivates a significant portion of the circulating hormone. Excretion is mainly renal.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary 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: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C).
Do not freeze.

5.4 Nature and composition of immediate packaging

Type I (10 ml) or type II (50 ml) glass vials sealed with a chlorobutyl stopper and an aluminium cap.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Eurovet Animal Health B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10989/044/001

8. DATE OF FIRST AUTHORISATION

01/10/1990

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

13/11/2024

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).