SUMMARY OF PRODUCT CHARACTERISTICS

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.

Excipient:

Chlorobutanol hemihydrate (preservative)	4.75 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

A clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

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

4.3 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 any of the excipients.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions sometimes occur.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

For intramuscular or intravenous injection.
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

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

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.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Systemic hormonal preparations, posterior pituitary lobe hormones, oxytocin.
ATCvet code: QH01BB02.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorobutanol hemihydrate
Glacial acetic Acid
Sodium Acetate trihydrate
Sodium chloride
Water for injection

6.2 Incompatibilities

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

6.3 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.

6.4. Special precautions for storage

Store in a refrigerator (2°C -8°C).

Do not freeze.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7. MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

VPA 10989/044/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1990

Date of last renewal: 21st July 2010

10 DATE OF REVISION OF THE TEXT

December 2016