

PART III

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.
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Excipients:

Chlorobutanol hemihydrate (preservative)	4.75 mg
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3. PHARMACEUTICAL FORM

Solution for injection.

4. PHARMACOLOGICAL PROPERTIES

Summary presentation of the active ingredient

Pharmacotherapeutic group: Hormone

ATCvet code: QH01BB02

Oxytocin is a naturally occurring hormone present in the female and male organism of all mammalian species. Its chemical structure is a nonapeptide.

4.1 Pharmacodynamic properties

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.

4.2 Pharmacokinetic properties

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. CLINICAL PARTICULARS

5.1 Target species

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

5.2 Indications for use

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

5.3 Contraindications

Do not use oxytocin in case of:
incomplete dilation of the cervix, any form of obstructive dystocia, known cases of hypersensitivity to the active ingredient.

5.4 Undesirable effects (frequency and seriousness)

Hypersensitivity reactions sometimes occur.

5.5 Special precautions for use

If uterine hyperactivity occurs, oxytocin administration should be immediately discontinued. Oxytocin should not be given simultaneously by more than one route of administration.

5.6 Use during pregnancy and lactation

Not to be used during pregnancy. Only when the animal is full term should the product be administered.

5.7 Interaction with other veterinary 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.

5.8 Posology and method of administration

For intramuscular or intravenous injection:

Obstetrics

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

Milk letdown

- Queen and bitch: 1 - 10 I.U.
- Ewe, goat and sow: 5 - 20 I.U.
- Cow and mare: 10 - 40 I.U.

5.9 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.

5.10 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. If uterine hyperactivity occurs, oxytocin administration should be immediately discontinued.

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.

5.11 Withdrawal period

Meat and milk zero days. Animals may be slaughtered for human consumption during treatment and milk may be taken from animals during treatment.

5.12 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.

6. PHARMACEUTICAL PARTICULARS

6.1 Major incompatibilities

This product is not intended for mixing with other components.

6.2 Shelf life

Shelf life: 3 years.
In use shelf life: 28 days

6.3 Special precautions for storage

Store between 2-8°C, do not freeze.

6.4 Nature and contents of container

Glass type I (10 ml) or II (50 ml) vials sealed with a chlorobutyl stopper and an aluminium cap containing a colourless aqueous solution.

6.5 Special precautions for the disposal of unused medicinal product or waste materials, if any

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7. **NAME OR CORPORATE NAME AND ADDRESS OR REGISTERED PLACE
OF BUSINESS OF THE MARKETING AUTHORISATION HOLDER**

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

8. ADDITIONAL INFORMATION

8.1 Marketing authorisation number

VPA 10989/44/1

8.2.1 Date of approval of SPC

1st October 2005

8.2.2 Date for revision of SPC