SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytocin-S, 10 iu/ml, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:

Oxytocin 10 iu
(equivalent to 0.018 mg oxytocin)

Excipients:
Chlorbutanol 5 mg
(Added as Chlorbutanol hemihydrate 5.254 mg as a preservative)

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection
Clear aqueous solution

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

Injections with this product will initiate strong, regular and purposeful contractions of the uterine muscle especially in the later stages of pregnancy and post-partum. It also evokes the 'let-down' of milk although it has no action on the smooth muscles of the gut or urinary bladder, nor is it effective in the treatment of diabetes insipidus. The absence of vasopressor and antidiuretic effects make it particularly suitable for obstetric use (stimulation of parturition, promotion of uterine involution and control of post-partum haemorrhage) and the treatment of agalactia.

The product is indicated for:
- stimulation of uterine contraction to facilitate parturition in the presence of a fully dilated cervix
- to promote involution of the post-parturient uterus and thus aid the passage of

retained placenta
- to aid in control of post-partum haemorrhage
- promotion of milk 'let-down' in cases of agalactia and to facilitate ‘stripping out’ of infected quarters in the treatment of mastitis in cows.

4.3 Contraindications

1. When the product 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.
2. The product is contraindicated in any form of obstructive dystocia.
3. Excessive doses of the product may delay parturition by producing incoordinated uterine contractions which interfere with the progress of the foetus especially in multiple pregnancies.
4. The effects of daily dosages of 100 iu or more (to facilitate ‘stripping out’ of infected quarters in the treatment of mastitis in cows) on the oestrous cycle have not been fully investigated and the cycle length may be altered.
5. 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 'let down' or uterine contractions.

4.4 Special warning for each target species

None

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals

i. Special precautions for use in animals

Use aseptic precautions.

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

Pregnant or lactating women should avoid handling the product as it could cause smooth muscle (e.g. uterine) contraction.
When administering the product, care should be taken to avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Used to promote parturition and milk let-down. Not to be used in late pregnancy unless the intention is to promote parturition.

4.8 Interaction with other medicinal products and other forms of interaction

Stimulation of beta-adrenergic receptors may reduce the effect of oxytocin on the uterus or mammary gland.

4.9 Amounts to be administered and administration route

The product should normally be given by deep intramuscular injection.

Species	**Dosage**	**mls**
Queen	2-5 iu	0.2-0.5 ml
Bitch	2-10 iu	0.2-1.0 ml
Ewe, goat, sow	2-10 iu	0.2-1.0 ml
Mare	10-40 iu	1.0-4.0 ml
Cow *Indications other than mastitis as listed in section 4. For mastitis treatment see below.*	10-40 iu	1.0-4.0 ml

Adjunct to mastitis treatment in cows:
A single dose of up to 80 iu (8 ml) prior to stripping out before first mastitis treatment followed by repeated doses of 20 iu (2 ml) prior to each stripping out 2 or 3 times daily while mastitis treatment continues.

Where the intravenous route is used, these doses should be reduced to one-quarter of the intramuscular dose and the injection given slowly at a dilution of 1 in 10 Water for Injections Ph.Eur. Where speed of onset is not a priority, the product may be given by the subcutaneous route.

A low initial dosage is recommended by any route as repeat administration is permissible.

Large doses may be employed in post-parturient animals.

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

Excessive doses might cause uncoordinated uterine contractions (also refer to section 4.3).

4.11 Withdrawal period(s)

Cattle, sheep, pigs, horses and goats: Meat – Zero days
Cattle, sheep and goats: Milk – Zero hours

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QH01BB02

Pharmacotherapeutic group: Pituitary and hypothalamic hormones and analogues, Posterior pituitary lobe hormones, Oxytocin and analogues

5.1 Pharmacodynamic properties

The active ingredient is synthetic oxytocin which is a nature-identical nanopeptide. Oxytocin is a hormone which enhances the contractility of the uterus muscle especially during parturition and post partum, it also evokes let-down of milk. It has no vasopressor or antidiuretic activity.

5.2 Pharmacokinetic particulars

Following injection, oxytocin has a rapid onset of activity as physiological effects are usually detected within minutes following administration. Oxytocin is cleared very fast, as its mean half life of distribution is around 2 minutes while its half life of elimination is around 12 minutes.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorbutanol hemihydrate
Sodium chloride
Acetic acid or sodium hydroxide used for pH adjustment
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with any 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 (between +2^{o}C and +8^{o}C). Protect from light.

6.5 Nature and composition of immediate packaging

Colourless glass (Type II) vial, closed with bromobutyl rubber stoppers and sealed with aluminium caps.
Pack size: 25 ml.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

Intervet International B.V.
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4084

9. DATE OF FIRST AUTHORISATION

29 July 1994

10. DATE OF REVISION OF TEXT

December 2024

Approved 10 December 2024
Gavin Hall