1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytocin aniMedica, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance
Oxytocin 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	3.00 mg
Ethanol (96 per cent)	40.10 mg
Acetic Acid 99%	
Water for Injections	

A clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

This veterinary medicinal product is indicated for obstetric use (stimulation of parturition, promotion of uterine involution and control of post partum haemorrhage) and the treatment of agalactia in mares, cows, sows, ewes, goats, bitches and cats.

3.3 Contraindications

Do not use in any form of obstructive dystocia.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

When the veterinary medicinal product is used as an aid in parturition cervical dilation must be confirmed prior to administration to prevent risk of foetal death and possible uterine rupture.

Excessive doses of the veterinary medicinal product may delay parturition by producing uncoordinated uterine contractions which interfere with the progress of the foetus especially in multiple pregnancies.

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

The veterinary medicinal product should not be administered by pregnant women.
Care should be taken to avoid accidental self-injection.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 and lactation:
The veterinary medicinal product is indicated for use, as appropriate, during parturition and lactation.
The use is not recommended in the prepartum pregnant animal.

3.8 Interaction with other medicinal products and other forms of interaction

There are no specific interactions, and this veterinary medicinal product may with benefit be used concurrently with other veterinary medicinal products e.g. with antibiotics in the treatment of endometritis.

3.9 Administration routes and dosage

Subcutaneous or intra-muscular use.

Mares and cows:	4 – 6 ml
Sows:	1 – 3 ml
Ewes and goats:	1 – 2 ml
Bitches and cats:	0.25 – 1 ml

For treatment of agalactia the stated higher dosage level should be used.
The veterinary medicinal product may be administered by slow intravenous injection at dose rates one third of the above.

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

This is a relatively non-toxic active. Enhanced dose rates will not result in proportionally increased pharmacological effects and there are no other toxic effects. Treatment of overdose is palliative and there are no specific antidotes.

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

Horses, cattle, pigs, sheep, goats:
Meat and offal: Zero days.
Milk: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QH01BB02

4.2 Pharmacodynamics

Oxytocin is a hormone of the posterior lobe of the hypophysis. It influences the rhythmic contraction of the oxytocin sensitive smooth muscle apparatus. Of special significance is the increase of strength and frequency of the uterine contractions at the beginning of labour.

In the lactating cow the myoepithelial cells, which cover the alveoli of the mammary glands, are contracted by the influence of oxytocin and the milk is passed into the milk ducts.

The veterinary medicinal product is a sterile, aqueous, protein-free injectable solution of synthetic oxytocin which corresponds chemically as well as pharmacologically with naturally occurring oxytocin.

The veterinary medicinal product is free from vasopressin.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal 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: 7 days.

5.3 Special precautions for storage

Store at 2-8 °C.
Protect from light.

5.4 Nature and composition of immediate packaging

Colourless glass vials (Type HK1) with a grey bromobutyl rubber stopper and an aluminium flanged cap in a cardboard box.

Pack sizes:
10 ml
12 x 10 ml

Colourless glass vials (Type HK2) with a grey bromobutyl rubber stopper and an aluminium flanged cap in a cardboard box.

Pack sizes:
50 m1
12 x 50 ml

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

aniMedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10826/004/001

8. DATE OF FIRST AUTHORISATION

01/10/1999

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

14/04/2026

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).