Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytocin aniMedica

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Oxytocin	10	I.U. (Voegtlin units)

Excipients

Chlorobutanol hemihydrate	3.00	mg
Ethanol (96 %)	40.10	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

Equine, Bovine, Porcine, Ovine, Caprine, Canine and Feline.

4.2 Indications for use, specifying the target species

Oxytocin aniMedica is indicated for obstetric use (stimulation of paturition, promotion of uterine involution and control of post partum haemorrhage) and the treatment of agalactia in the mare, cow, sow, ewe, goat, bitch and cat.

4.3 Contraindications

Use in any form of obstructive dystocia.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

When Oxytocin aniMedica 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 Oxytocin aniMedica 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

Pregnant women should avoid direct contact with the product. Care should be taken to avoid accidental self-injection.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

The product is indicated for use, as appropriate, during parturition and lactation. It should not be used in the pre-partum pregnant animal.

4.8 Interaction with other medicinal products and other forms of interactions

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

4.9 Amounts to be administered and administration route

Administered by subcutaneous or intra-muscular injection.

Mare & Cow 4 - 6 ml
Sow 1 - 3 ml
Ewe & Goat 1 - 2 ml
Bitch & Cat 0.25 - 1 ml

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

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

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.

4.11 Withdrawal period(s)

Meat & offal: zero days. Animals may be slaughtered for human consumption during treatment.
Milk: zero days. Milk may be taken from treated animals during treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QH01BB02
Pharmacotherapeutic group: Systemic hormonal preparations; Posterior pituitary lobe hormones; Oxytocin.

5.1 Pharmacodynamic properties

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 milkducts.

Oxytocin aniMedica is a sterile, aqueous, protein-free injectable solution of synthetic oxytocin which corresponds chemically as well as pharmacologically with naturally occuring oxytocin.

Oxytocin aniMedica is free from vasopressin.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorobutanol Hemihydrate
Ethanol (96 %)
Acetic Acid 99%Water for Injections

6.2 Major incompatibilities

In the absence of compatability studies, this veterinary medicinal 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 yearsShelf-life after first opening the immediate packaging: 7 days

6.4 Special precautions for storage

Store at 2-8 oC. Protect from light.

6.5 Nature and composition of immediate packaging

10 ml Vials: colourless glass vials (Type HK1)
50 ml Vials: colourless glass vials (Type HK2)

Stopper : Rubber stopper of grey bromobutyl rubber.
Cap : Aumminium flanged cap.
Pack sizes: 10 ml, 12 x 10 ml
50 ml, 12 x 50 ml

Not all pack sizes may be marketed

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10826/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

December 2021