SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXITOVET 10 IU/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Oxytocin .....10.00 IU

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	5.00 mg
Sodium chloride	
Ethanol (96 per cent)	
Acetic acid, glacial (E 260) (for pH adjustment)	
Water for injections	

Clear and colourless solution, free from visible particles

3. CLINICAL INFORMATION

3.1 Target species

Cattle (cows), pigs (sows), horses (mares).

3.2 Indications for use for each target species

Cows, sows and mares:
Induction to parturition.
Uterine inertia or atony.
Uterus involution after caesarean section and reduction of haemorrhages.
Expulsion of afterbirth and exudates after parturition.
Milk ejection after parturition.
Agalactia in sows.
Induction of the expulsion of exudates in cases of chronic pyometritis and endometritis

Adjuvant treatment to antibiotic therapy of acute and chronic mastitis, to induce the expulsion of residues and facilitating drainage

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of dystocia due to abnormal presentation, foetal-pelvic disproportion or any other type of mechanic obstruction.
Do not use in animals with cardiovascular diseases.
Do not use in females with predisposition to uterine rupture.
Do not use in in cases of non-dilation of the uterine cervix (inducting of parturition).

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:

Intravenous injection should be very slow and preferably with glucose or gluco-saline.
Administer with caution in cases of toxaemia.
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.

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

This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to oxytocin should administer the veterinary medicinal product with caution.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
In case of spillage on skin or eyes, wash immediately with plenty of water.
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.

Special precautions for the protection of the environment:

Not applicable

3.6 Adverse events

Cows, sows and mares

'Undetermined frequency (cannot be estimated from the available data)	Allergic reactions

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 also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Do not use in pregnant females before the time of parturition

3.8 Interaction with other medicinal products and other forms of interaction

Corticosteroids, sympathomimetic vasoconstrictors, anaesthetics, calcium, oestrogens and prostaglandins may enhance its effects.

3.9 Administration routes and dosage

Obstetrics (subcutaneous, intramuscular or intravenous use):

Cows: 75 - 100 IU (equivalent to 7.5 - 10 ml of product)
Mares: 75 - 150 IU (equivalent to 7.5 - 15 ml of product)
Sows: 35 - 50 IU (equivalent to 3.5 - 5 ml of product)

Milk ejection (preferably intravenous use):

Cows and mares: 10 - 20 IU (equivalent to 1 - 2 ml of product)
Sows: 5 - 20 IU (equivalent to 0.5 - 2 ml of product)
The administration may be repeated every 30 minutes, if considered necessary by the veterinarian.

The stopper should not be punctured more than 50 times.

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

Hyperstimulation and myometrial spasm, premature separation of the placenta, bradycardias and arrhythmias, and even maternal and foetal death can occur.

Water retention intoxication, characterised by convulsions, coma and even maternal death, can occur after intravenous administration of large doses over long periods.
Postpartum haemorrhage may occur and should be treated symptomatically.
Foetal death may occur.

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

3.12 Withdrawal periods

Meat and offal: zero days
Milk: zero hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH01BB02

4.2 Pharmacodynamics

Hormone synthesised in the hypothalamus and released in the posterior lobe of the pituitary gland, obtained synthetically, belonging to the oxytocics group.
It acts by selectively stimulating the motor activity of the uterus, increasing contractions and tone. The uterine response to oxytocic hormone is affected by the action of female sex hormones; it enhances uterine motility if the organ is dominated by oestrogen (oestrus, proestrus and late gestation), but not if it is dominated by progesterone (oestrus and gestation). Oxytocin also causes contraction of the myoepithelial cells of the mammary acini, causing milk ejection.

4.3 Pharmacokinetics

After parenteral administration, it is rapidly absorbed, and partially bound to plasma proteins. It is metabolized rapidly in the body by the action of oxytocinase, present in blood serum during pregnancy (formed in placenta) and tissues (especially liver and kidney), with its rapid and transient effects. The half-life in blood is 2 - 3 minutes. It is eliminated by urine and, in lactating animals, also by mammary gland.

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 medical product as packaged for sale: 2 years.
Shelf life after first opening the immediate package: 28 days.

5.3 Special precautions for storage

Store below 25 ºC.

5.4 Nature and composition of immediate packaging

Polypropylene vial, with bromobutyl rubber stopper and aluminium cap.

Pack sizes:
Cardboard box containing one 100 ml vial.
Cardboard box containing one 250 ml vial.

Not all pack sizes may be marketed.

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

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.

Medicines should not be disposed of via wastewater or household waste.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

SUPER'S DIANA S.L.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

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

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).*