

For Veterinary Use Only.



Pitosal[®]

Solution for Injection

Veterinary Synthetic Oxytocin

COMPOSITION:

Pitosal Solution for Injection is a clear, colorless, odorless and viscous solution containing 10IU synthetic oxytocin per each ml.

PHARMACOLOGICAL PROPERTIES:

The active substance of **Pitosal Solution for Injection**, oxytocin, is a synthetic hormone causing milk secretion and uterus contraction excreted from the posterior lobe of the pituitary gland. It generates rhythmic contractions in uterus smooth muscles in all species. The activity of uterus produced by oxytocin depends mainly on the status of reproductive cycle. When uterus is less sensitive to oxytocin in the earlier periods of normal pregnancy the sensitivity increases in the final periods of pregnancy. Oxytocin is associated with the secretion of milk. Mammary glands increase the contractions of smooth muscle cells and create their effect. Oxytocin is released depending on the stimulations in the nervous system. Milk secretion is also associated with psychological or teat stimulation. The neural stimulation observed during the delivery arises from vagina, cervix and uterus. The stimulation of reproductive ducts during mating facilitates oxytocin secretion and thus, proceeding of sperma throughout reproductive duct. There are receptors present in the smooth muscles of uterus which oxytocin binds to. Oxytocin binds to these receptors and demonstrates its effect. Receptors are increased during pregnancy. Oxytocin is rapidly and well absorbed when administered parenterally. The half life is between 12 and 17 minutes. It is rapidly catabolized by the enzymes in liver and kidneys and excreted as inactive metabolites through kidneys.

AREA OF USE / INDICATIONS

Pitosal Solution for Injection,

is indicated in all domestic animals for the following;

- Accelerating normal delivery
- Accelerating taking the foetus outside in animals with uterus laziness Increasing uterus contractions.
- Discharging the uterus content and placental residues after delivery.
- Preventing post-partum uterus atonia and retentio secundinarum.
- In metritis.
- The intrauterine injection performed after taking the foetus out in caesarean operation accelerates the involution of the uterus.
- In the cases of uterus prolapse, the injections performed on different areas of the organ reduce congestion and increase the contractions of the turned uterus facilitating the reverting of the organ.
- It acts on the smooth muscles of mammary glands in the lactation and ensures the secretion of milk.
- In mastitis cases in which the breasts have to be ejected.

USAGE AND DOSAGE:

Pitosal Solution for Injection is administered subcutaneously (SC), intramuscularly (IM) or intravenously (IV).

In practical, administration in small doses at intervals of 30 minutes is more effective than a high dose administered outright.

Species	Subcutaneously or Intramuscularly	Intravenously
Mare	6-10 ml (60 - 100 IU)	1-2 ml (10 - 20 IU)
Cow	6-10 ml (60 - 100 IU)	1-2 ml (10 - 20 IU)
Sheep-Goat	2 - 4 ml (20 - 40 IU)	0.5 - 2 ml (5 - 20 IU)
Female dog	0.5-2.5 ml (5 - 25 IU)	0.2-1 ml (2 - 10 IU)
Female cat	0.5-1 ml (5 - 10 IU)	0.1-1 ml (1 - 10 IU)

SPECIFIC CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES:

Ensure that the cervix is opened before administering oxytocin. Otherwise, fatal death or uterus tearing may occur. Administer with special care to toxæmic animals. Intravenous injections should be performed slowly and mixed preferably with physiologic saline water or glucose solution. In case oestrogen is reduced or when it does not reach the adequate level, the effect of oxytocin is declined over uterus. Applying only oxytocin injections without performing the necessary intervention in the cases of coming and position disorders of the offspring may result in uterus tearing or death of foetus. The physiological level of adrenalin may reduce the effect of oxytocin over uterus and mammary glands. Thus, avoid creating stress in animals during oxytocin administration. Administration of 20 IU doses at intervals of 30 minutes prevents the severe and irregular contractions that may be created by an administration at a high dose outright.

UNDESIRE/SIDE EFFECTS:

Anxiety, excessive straining, abdominal pain and perspiration may be observed in horses following injection.

Use during pregnancy: It is contraindicated in advanced pregnant animals whose time has not come to deliver; without adjusting the position of the offspring in hard deliveries and in the cases where cervix is not opened adequately. Avoid using in the first and second steps of delivery if the pain proceeds even if slowly. Avoid using in the cases of retentio secundinarum in horses.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE:

In case of overdose, side effects may be seen such as uterus hypercontractibility, uterus tetani or spasm. In cases of high dose administration for long-term periods, reduction in the length of oestrous may be observed in cows. When administered in higher amounts, it affects vascular smooth muscles and decreases systolic and diastolic blood pressure resulting in skin rash and increment of heart rates. There is no antidote. Symptomatic treatment should be performed, if required.

DRUG INTERACTIONS:

Avoid using with corticosteroids, vasoconstrictors, sympathicomimetics, general anesthetics and progesterone. Calcium and estrogens increase its effect.

WARNINGS ON DRUG RESIDUES IN FOOD:

Purification Time of Drug Residues (p.t.d.r.): is "0"(zero) days

CONTRAINDICATIONS:

Avoid using in animals with sensitization for the drug; for the distinctively abnormal deliveries due to disproportion of pelvis and foetus or any mechanical occlusion; in animals with cardiac and vein disorders; in the ones which are predisposed to tearing of uterus; in the cases where the position of foetus is not adjusted and in pregnant animals until the delivery time starts.

GENERAL WARNINGS: It is sold with Veterinary Surgeon prescription. Keep out of reach of children. Protect from light.

PRECAUTIONS TO BE TAKEN BY THE USER AND WARNINGS FOR VETERINARY SURGEONS:

Oxytocin is absorbed through mucous membranes at high rates. Therefore, using gloves and glasses prevents the contamination of the user.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES:

Dispose of empty bottles and injection apparatus properly after use.

STORAGE CONDITIONS AND SHELF LIFE:

Store at 2-15°C in dry environment.

Shelf life is 3 years as of the production date.

COMMERCIAL PRESENTATION FORM INDICATING THE QUALITY AND QUANTITY OF THE PACKAGE:

Presented to the market in 10, 20 and 50ml transparent vials in cardboard boxes.

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon's prescription in pharmacies and veterinary surgeries.

APPROVAL DATE OF PACKAGE INSERT: 25.04.2007

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS MARKETING AUTHORIZATION DATE AND NO:

25.04.2007 - 18/015

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlık Ürünleri San. ve Tic. A.Ş

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NAME AND ADDRESS OF MANUFACTURER COMPANY:

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