For Veterinary Use Only.

BELLADONE®

Solution for Injection

Veterinary Anticholinergic

COMPOSITION:

Belladone Solution for Injection is a clear, colorless, odorless, liquid solution containing in each ml 2 mg of atropine sulfate.

PHARMACOLOGIC PROPERTIES:

Atropine, a parasympatholytic agent, affects by inhibiting the appearance of characteristic effects of acetylcholine. Efficiency appears as inhibition of motion of muscarine and acetylcholine in muscarinic and nicotinic subunits. Efficiency of atropine is reversible and sustainability of efficiency can be possible only by having sufficient concentration in the environment. Atropine sets in competitive antagonism in digestive system, urinary system and uterus smooth muscles through binding to receptors to which ACh would bind. Again in organic phosphoric insecticide poisoning, it acts as an antidote by not only reducing parasympathomimetic effect of these insecticides but also causing an increase in deadly organophosphor amount. It is absorbed rapidly when administered parenterally. It is excreted in urine in a significant amount, while another significant amount is metabolically transformed.

AREA OF USE / INDICATIONS:

Belladone Solution for Injection stimulates respiratory and cardiac movements, and has an anti-spasm effect on gastrointestinal system, uterus, ureters, and smooth muscles of urinary tract when administered parenterally due to its parasympatholytic effects. For such effects, atropine is used as a stimulator in cardiac and respiratory strokes and heat strokes, as an antispasmodic against pain, as premedication before general anesthesia and as an antidote for poisoning by insecticides of organic phosphoric and carmabate groups.

USAGE AND DOSAGE:

Pharmacologic dose of atropine sulfate being the active substance of Belladone Solution for Injection is 0.03 to 0.06 mg / kg c.a. However, dosage may vary according to animal species. Pharmacologic dose varies between 0.03-0.1 mg / kg l.w. in cats and dogs. The dose is higher while administered as antidote. An average dose of 0.04 mg/kg c.a SC is administered for general indications, while an intravascular dose of 0.1-0.5 mg / kg c.a is administered for insecticide poisoning of organophosphoric and carbamate groups. Dose repetition should be made depending on regression of poisoning symptoms and by monitoring atropinization findings. For administration as premedication before anesthesia, it is administered intravascularly with a dose of 0.1 mg / kg c.a in horses, 0.2 mg / kg c.a in sheep and goats and 0.045-0.06 mg / kg c.a in cats and dogs.

SPECIES	**SC (General Administrations)**	**IV (Insecticide Poisonings)**
Horse, cattle	8 -20 ml (400-600 kg c.a)	20-40 ml (a dose of 0.1 -0.5 mg/ kg c.a)
Calf, foal	2-10 ml (60-300 kg c.a)	4-20 ml (a dose of 0.1 -0.5 mg/ kg c.a)
Sheep, goat	2- 4 ml (60-120 kg c.a)	6-15 ml (a dose of 0.2 -0.5 mg/ kg c.a)
Dog	0.2-2 ml (6-30 kg c.a)	1-5 ml (a dose of 0.1 -0.5 mg/ kg c.a)
Cat	0.1 -0.2 ml (2-6 kg c.a)	0.5-1 ml (a dose of 0.1 -0.5 mg/ kg c.a)

DRUG INTERACTIONS:

Efficiency of atropine is increased when used concomitantly with other drugs such as phenothiazine and procainamide. On the other hand, concomitant use with cholinergic drugs reduces efficiency. It is incompatible with asepromazine, chlorpromazine, heparin, and metohexital sodium. Atropine may affect absorption of other drugs as it reduces gastrointestinal motility. When used with parasympathomimetics (i.e. choline esters, cholinergically-effective alkaloids, acetylcholine esterase inhibitors), they antagonize the effect of each other.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE:

For administrations other than insecticide poisonings, high doses may cause an increase in body temperature, tachycardia, and visual disorders due to pupil expansion . There is no specific antidote for atropine poisonings. Although parasympathomimetics such as neostigmine, arecholine and pilocarpine can be used for preventing peripheral effects, these drugs have no efficiency against serious central stimulations.

WARNINGS ON DRUG RESIDUES IN FOOD:

Withholding Period (WHP): Zero (0) day for flesh and milk.

CONTRAINDICATIONS:

It should not be used with another parasympatholytic agent. It should not be administered in cases of tachycardia, glaucoma or cornea ulcers and intestinal motility decrease.

Use during pregnancy: Use of the drug is not recommended during pregnancy except obligatory cases as its use during pregnancy has been inadequately studied.

WARNINGS FOR NON-TARGET SPECIES:

It is contraindicated in poultry.

SPECIFIC CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES:

Recommended doses should not be exceeded. Intravascular injection should be administered slowly. It should be noted that intestinal motility can be decreased in horses. It is not recommended as preanesthetic in cattle as long-term anorexia and ruminal inactivity is observed. For organic phosphoric insecticide poisonings ,a quarter of the amount to be administered should be given intravascularly in a rapid way, and the remaining part should be administered intravascularly or subcutaneously and slowly by monitoring the status of the animal until atropinization is observed (pupil expansion, disruption of salivation, quickening of pulse, etc.). Administration can be continued for a few days according to the status of the animal with intervals of 3-6 hours.

GENERAL WARNINGS

Consult your Veterinary Surgeon before using and in case an undesired effect is observed. Keep out of reach of children.

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

Wash with plenty of water if the product contacts with skin. In case of contact with eyes, it may cause blurred vision due to pupil expansion.

STORAGE CONDITIONS AND SHELF LIFE:

Store in 15-25 ℃ and protect from light. Shelf life is 3 years from production date.

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

Offered for sale in cardboard boxes, 20 ml, 50 ml amber vials and 10 ml ampoules.

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon prescription in pharmacies and veterinary surgeries (VSP).

APPROVAL DATE OF PACKAGE INSERT: 06.12.2004

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

28.09.1999-9/875

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

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