Vetaş Atropin %0.2

Solution for Injection

support you look for

ROUTE OF ADMINISTRATION AND DOSAGE

25-500 µg/kg body weight

The low doses are used more for parasympatholytic effect and preanaesthetic purposes and high doses are used in anticholinesterase poisonings.

It is used as follow in anticholinesterase poisonings;

Severe cases: Some (quarter) of the required dose is administered by intramuscular route or slow intravenous route and the remain dose by subcutaneous route.

Less severe cases: Total of the dose is administered by subcutaneous route.

Use during pregnancy and lactation:
Use in pregnant and lactating animals is not recommended.

Pack size **20 ml**

Shelf Life **48 months**

WITHDRAWAL PERIOD
It should not be used in edible animals.

COMPOSITION VETAŞ ATROPIN 0.2% Solution for Injection is a sterile, clear, colourless solution with a characteristic odour and each ml contains 2 mg atropine sulfate as active substance and 15.7 mg benzyl alcohol as excipient. PHARMACOLOGICAL PROPERTIES Pharmacodynamic properties: Atropine is a tertiary amine alkaloid with peripheral and central antimuscarinic effect. It stimulates the central nervous system at first and then suppresses and has an antispasmodic effect on smooth muscles. It leads to peripheral vasodilatation seen with the blood pressure increase and slight respiratory stimulation. It suppresses the vagus and thus accelerates the heart rate. It is used for decreasing of bronchial secretion and salivation and for premedication in anaesthesia by decreasing the vagal inhibition. It suppresses gastric acid and pancreatic secretion. Its competitive antagonistic effect in the organs on acetylcholine is related to dosage. Saliva and sweat glands are sensitive to atropine at low doses. Vagolitic effect on heart occurs at high doses. Digestive system and urinary system are the least sensitive to atropine. It is also used for bradycardia and management of the asystole situations. Atropine and the other antimuscarinic drugs inhibit muscarinic side effects of the anticholinesterases, therefore they reverse non-depolarize effects of the neuromuscular blocking agents. Atropine decreases tremor and muscle hardening like in Parkinsonism. It also has cycloplegic and mydriatic properties. It is used as a partial antidote in organic phosphorus poisoning. Pharmacokinetic properties: It is rapidly absorbed after the administration. It distributes to whole body and its half-life is 2.5 hours. It is excreted via urine as partially unchanged and via milk also. AREA OF USE/INDICATIONS It is used in horse, cat and dog. It is used as a partial antidote in anticholinesterase poisonings (such as phosphoric esters, carbamates, organic chlorinated compounds, etc), as preanaesthetic in order to prevent bradycardia and bronchial secretion in general anaesthesia, as spasmolytic in smooth muscles (such as digestive system, urinary system, uterus, bronches, bile duct, etc.), as a cardiac stimulant in cases of atrioventricular block or sinus bradycardia. It is also used for reducing bronchial secretion and as a respiratory stimulant. ROUTE OF ADMINISTRATION AND DOSAGE: The use of atropine for parasympatholytic purposes in general by subcutaneous route with the doses below: It is administered at the dose of 25-500 µg / kg body weight in general as well as related to the physician's choice. The low doses are used more for parasympatholytic effect and preanaesthetic purposes and high doses are used in anticholinesterase poisonings. The administration can be repeated in every 6-8 hours until recovery, in cases of atrioventricular block or sinus bradycardia. It is used in anticholinesterase-effective poisonings as follows; Severe cases: Some (quarter) of the required dose is administered by intramuscular route or slow intravenous route and the remain dose by subcutaneous route. Less severe cases: Total of the dose is administered by subcutaneous route. Repetitive doses may be required according to severity of the poisoning. Administration interval is 3-4 hours in general, and also it is related to repetition frequency of severe or moderate symptoms. Atropine acts in minutes after the administration and this maximum effect may retard to 5-10 minutes after the administration. Atropine is also used in the treatment of heart blockade that may occur in xylazine anaesthesia in horse at the dose of 0.01 mg/kg body weight (0.5 ml / 100 kg body weight) by intravenous route. SPECIAL CLINICAL INFORMATION AND WARNINGS FOR TARGET SPECIES Hyperthermia should be considered in case of high environmental temperature. The animals administered atropine should be kept under clinical observation. While using ATROPINE for parasympatholytic purposes, special dose adjustment for each animal species and administering by subcutaneous route should be paid attention to in particular. Intravenous administration should be done slowly in poisonings with insecticides with organic phosphorus. Repeat dosing should be done by following the atropinization findings and according to regression of the poisoning symptoms. Due to long-term inappetency and decreased rumen motility in adult cattle, it should not be used as preanaesthetic. Use during pregnancy and lactation: The studies with animals it is showed that it is teratogenic and has no effect on reproductive system. However atropine may pass the placenta and blood-milk barrier, use in pregnant and lactating animals is not recommended. ADVERSE REACTIONS Effects of atropine are related to the dose. While the secretory glands are sensitive to low doses, higher doses are necessary for the vagolytic act on heart muscle. During the come out of anaesthesia, continuation of anticholinergic effect may be observed. Dry mouth, mydriasis, constipation, accommodation disorder, tachycardia, vomiting, abdominal swelling, urinary retention may occur. DRUG INTERACTIONS Atropine sulfate can be used together with the inhalation anaesthetics, barbiturates, xylazine, ketamine and azepromazine. There is a literature about use of the anticholinergics such as atropine with medetomidine or alpha-2 receptor agonists such as xylazine for sedative or premedication purposes in dogs may cause tachycardia and chronic hypertension. Atropine sulfate antagonizes the effect of metoclopramide. Quinidine, disopyramide, glutethimide, meperidine, procaine and procainamide increase the antimuscarinic effect of atropine. Amantadine, some antihistamines, butyrophenones and anticholinergic drugs such as phenothiazine increase anticholinergic effect of atropine. Atropine increases the toxic effects of ranitidine. It should not be used together with acepromazine maleate, chlorpromazine HCl, heparin sodium, alkalines, tannic acid and silver salts. OVERDOSE (SYMPTOMS, EMERGENCY PROCEDURES, ANTIDOTES) The symptoms occur from the combination of central and peripheral effects of the atropinization in overdose. Early symptoms are characterized with stimulation. Dry mouth, dysphagia, mydriasis, tachycardia, constipation, hyperpnea, muscle tremors, ataxia may be seen. Depression, cardiovascular collapse, apnea, paralysis and comma follow the stimulation at high doses. Anticholinesterases such as physostigmine can be used as antidote at 0.1-0.6 mg/kg dose by intravenous route. Stimulation can be alleviated with proper sedatives. Peripheral effects can be decreased with physiological antidotes such as pilocarpine. Medullar stimulators or artificial ventilation may be necessary in the following stages of overdose or poisoning with atropine. WITHDRAWAL PERIOD It should not be used in edible animals. CONTRAINDICATIONS It is not used in animals with sensitivity to atropine, intestinal obstruction or possible icterus. It is not used in cases of glaucoma, paralytic ileus or pyloric stenosis. It is not used in patients with heart failure, hyperthyroidism, hyperthermia and arrythmia. GENERAL WARNINGS Consult a veterinarian before use and in case of unexpected effects. Keep out of sight and reach of children. PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE MEDICINAL PRODUCT AND WARNINGS FOR PHYSICANS Necessary precautions should be taken to avoid of accidental self-injection. Take medical treatment immediately and show the leaflet and label to the doctor in case of injection to humans. Wash your hands after use. STORAGE CONDITIONS AND SHELF LIFE Shelf life is 48 months (36 months for 50 ml and 100 ml) from the manufacturing date. Store at room temperature below 25°C without refrigeration and freezing. Protect from sunlight. It should be used within 28 days after the first opening. The stopper of the product can be perforated for maximum 40 times. DISPOSAL OF WASTE MATERIALS AND WARNINGS FOR NON-TARGET SPECIES Any unused veterinary medicinal product or any waste material remaining from such a product should be disposed of as per the requirements of local laws. NATURE AND COMPOSITION OF IMMEDIATE PACKAGING It is presented in 20 ml, 50 ml and 100 ml Type II honey coloured glass bottles covered with aluminum-plastic white flip off cap and red rubber stopper in a cardboard box. TERMS OF SALE Sold only in veterinary clinics and pharmacies by veterinary prescription. MARKETING AUTHORISATION DATE AND NUMBER: 30.12.2003-13/014 NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER DEVA HOLDING A.Ş. Halkalı Merkez Mahallesi Basın Ekspres Cad. No:1 Küçükçekmece/İstanbul/TÜRKİYE Tel: +90 212 692 92 92 Faks: +90 212 697 34 89 e-mail: vetas@vetas.com.tr NAME AND ADDRESS OF THE MANUFACTURER DEVA HOLDING A.Ş. Çerkezköy Organize Sanayi Bölgesi, Karaağaç Mah. Atatürk Cad. No.32 59510 Kapaklı/Tekirdağ/TÜRKİYE Tel: +90 282 735 20 00 Fax: +90 282 758 16 83

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Please contact our company for more information. **DEVA HOLDİNG A.Ş.** Halkalı Merkez Mah. Basın Ekspres Cad. No:1 34303 Küçükçekmece / İSTANBUL - TÜRKİYE Tel: +90 212 692 92 92 Fax: +90 212 697 34 89 • www.vetas.com.tr

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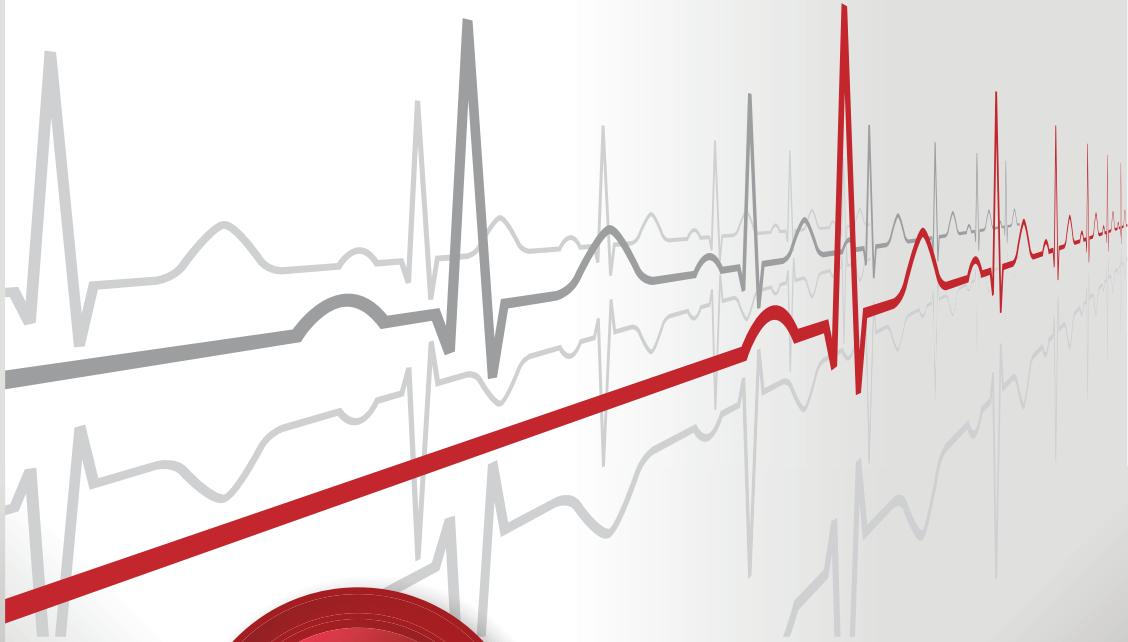

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COMPOSITION

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PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties:

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It suppresses the vagus and thus accelerates the heart rate.

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It suppresses gastric acid and pancreatic secretion. Its competitive antagonistic effect in the organs on acetylcholine is related to dosage. Saliva and sweat glands are sensitive to atropine at low doses.

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Digestive system and urinary system are the least sensitive to atropine. It is also used for bradycardia and management of the asystole situations.

Atropine and other antimuscarinic drugs inhibit muscarinic side effects of the anticholinesterases, therefore they reverse non-depolarize effects of the neuromuscular blocking agents.

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- As a preanaesthetic in order to prevent bradycardia and bronchial secretion in general anaesthesia
- As a spasmolytic in smooth muscles (such as digestive system, urinary system, uterus, bronches, bile duct, etc.)
- As a cardiac stimulant in cases of atrioventricular block or sinus bradycardia.
- Also used for reducing bronchial secretion and as a respiratory stimulant.