

Only for Veterinary Use

SEDINAL®

2% Solution for Injection

Veterinary Sedative Analgesic

COMPOSITION

Sedinal 2% is a clear, colorless solution for injection which contains 23.33 mg xylazine hydrochloride equivalent to 20 mg xylazine per 1 ml.

PHARMACOLOGICAL PROPERTIES

The active substance of Sedinal 2%, namely xylazine, is a thiazine derivative which exerts pain killing, sedative, hypnotic and muscle relaxant (skeletal muscle) effects. Xylazine is an α_2 -adrenergic antagonist. The effects on Central Nervous System (CNS) are exerted via activation or stimulation of α -adrenergic receptors such as α_2 -adrenergic receptors. With stimulation of α_2 -adrenergic receptors, xylazine has potent analgesic activity based on cessation of conduction of pain impulses. Xylazine also relaxes skeletal muscles by inhibiting intra-neural transmission impulses in CNS.

The product at the recommended dose has good tolerance to local or general anesthetic. Among pets, ruminants are the species with highest sensitivity to xylazine.

Peak plasma concentration is reached within 12-14 minutes following intra-muscular administration. Pharmacological activity occurs within 2-5 minutes following intravenous administration and within 10-15 minutes following intramuscular administration. Plasma half elimination time ranges between 23 to 60 minutes depending on the type of the administration including intramuscular (IM) or intravenous (IV) routes. Majority of active substance is eliminated in liver within 2-3 hours; 70 percent is excreted via kidneys and remaining 30 % is excreted in the form of glycuronide compounds via faeces.

AREA OF USE/INDICATIONS

Sedinal 2% is used for pain killing, sedative, hypnotic and muscle relaxing purposes as well as for premedication purposes (before administration of various anesthetic drugs) in horses, cats, dogs and wild animals.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

Unless otherwise advised by veterinary surgeon, the doses specific for particular species are mentioned below.

In Dogs:

Pharmacological dose is 1-3 mg/kg live body weight. It is administered via intramuscular or intravenous routes. It is sufficient for interventions not associated with severe pain (cases such as X-ray studies, wound therapy, bandage replacement, ear inflammation and dental scaling).

Combination with other drugs in dogs

1. With barbiturates

Intramuscular administration: 0.5-1 ml sedinal is administered, following premedication with atropine, concomitantly with 1/3 – ¼ diluted doses of barbiturate.

With Ketamine

Sedinal at dose of 1 ml / 10 kg live body weight can be concomitantly used with Ketamine at dose of 60-100 mg/10 kg live body weight. Due to effects inducing vomit, it should not be used for gastric obstruction, pharyngeal obstruction and herniation. Care should be taken for respiratory diseases.

In Cats:

Pharmacological dose is 2-4 mg/kg live body weight. It is administered via intra-muscular or intravenous routes. It is sufficient for interventions not associated with severe pain (cases such as X-ray studies, wound therapy, bandage replacement, ear inflammation and dental scaling).

Combination with other drugs in cats:

With barbiturates

If narcosis is required, narcotic agent can be administered during the sedation which occurs in 20 minutes after Sedinal is administered. Premedication with atropine is beneficial. When sedinal is administered, dose of barbiturate is reduced at the rate of 1/3 and 1/4, and intravenous administration should be slow.

Ether, Halothane / Fluothane

In order to prolong narcotic condition established using barbiturates, inhalation with ether or halothane or intubation narcosis is safe and efficient procedure.

3. With Ketamine:

Sedinal at dose of 0.1 mg/kg live body weight can be concomitantly used with Ketamine at dose of 5-15 mg/1kg live body weight.

In Cattle:

Pharmacological dose is intramuscular 0.05-0.3 mg/kg (0.25-1.5 ml/100 kg) live body weight. Based on required sedation, following different doses can be administered;

Dose	mg/kg	mg/50 kg	ml/50 kg
1	0.05	2.5	0.12
2	0.10	5.0	0.25
3	0.20	10	0.50
4	0.30	15	0.75

Dose 1:- Mild decrease in muscle tonus and sedation.

Dose 2: -Sedation, marked decrease in muscle tone and some analgesia. Dose 2:- Sedation, substantial decrease in muscle tone, slight analgesia. The animal usually remains standing. The animal generally stands.

Dose 3: -Deep sedation, further decrease in muscle tone and a useful degree of analgesia. Dose 3:- Deep sedation, substantial decrease in muscle tone, analgesia at the beneficial level. The animal lies down. The animal lies down.

Dose 4: -Very deep sedation, a profound decrease in muscle tone and a useful degree of analgesia. Dose 4:- Very deep sedation, deep decrease in muscle tone and analgesia. The animal is in state of

lying. Dose 2: -Sedation, marked decrease in muscle tone and some analgesia. The animal usually remains standing. Dose 3: -Deep sedation, further decrease in muscle tone and a useful degree of analgesia. The animal lies down. Dose 4: -Very deep sedation, a profound decrease in muscle tone and a useful degree of analgesia. The animal lies down.

Dose level should be adjusted according to the type of surgical operation.

In Horses:

Pharmacological dose is intravenous 0.8 mg/kg live body weight and intramuscular 1.5-3 mg/kg live body weight.

Combination with other drugs in horses:

Following combinations can be used in more painful and challenging surgical operations.

1. Chloral hydrate

8 g chloral hydrate for intramuscular 4 ml/100 kg live body weight of Sedinal

2. With barbiturates

Sedinal at intravenous dose of 5 ml/100 kg live body weight and 6-8 mg/kg pentobarbital or thiopental

In practice, following dose table can be used.

Target species	Intended Use	Dose (ml / 100 kg live body weight)		
		Intra-muscular	Subcutaneous	Intravenous
Calve	Sedation, hypnotic effect (transportations, artificial insemination etc.)	0,25	0,08-0,12	
	Minor surgical operations, muscle relaxant and pain killing effect	0,5	0,2-0,25	
	Major surgical operations, muscle relaxant and pain killing effect	1,0	0,35-0,5	
Horse	Major surgical operations, muscle relaxant and pain killing effect	7,5-15		4,0
		Dose (ml / 10 kg live body weight)		
Dog	Interventions not associated with very severe pain	0,5-1,5		0,5-1,5
		Dose (ml / kg live body weight)		
Cat	Sedation, interventions not associated with very severe pain	0,1-0,2	0,1-0,2	0,1-0,2

Wild animals

Dose table for wild animals with no nutritional value or that cannot be considered as human food (for animals residing in zoo) (intramuscular)

Species of the Animal	Sedative dose (mg/kg)	Hypnotic dose (mg/kg)	General dose (mg/kg)
Primates	0.5-1	2-5	-
Deer species – Reindeer – Antelope - Impala	0.5 1.5 1	2 3 3	- - -
Wolf	3-5	7-8	-
Bear	2-6	8-10	-
Elephant	-	0.15-0.2	-
Camel	0.1	0.5	-
Llama	0.2-0.5	1-2	-
Reptilian	-	-	0.1-1.25
Felidae – Lion, Leopard, Tiger, Cheetah	- -	8-10 -	- 1*
Wild birds, Falcon, Hawk, Owl	-	-	2*
Parrot	-	-	1.5*
Rabbit	-	-	4-8
Weasel	-	-	2.2
Lab. Animal – Gerbillus, Guinea pig, Rat	- -	- -	2-5* (Intraperitoneal) 7-15*
Ostrich	-	-	

* Treatment is maintained with ketamine following these doses.

SPECIFIC CLINICAL INFORMATION AND WARNINGS FOR TARGET SPECIES

Intended use of Sedinal 2% requires different doses and practices in different animals as indicated in dose table. Degree and maintenance of effect in administered animals is dependent on the dose and administration route. Administrations to subcutaneous tissue, loose connective tissue or fat tissue result with slow absorption and rapid excretion and accordingly, desired effect may not be obtained. Moreover, avoid disturbing animals during hypnotic condition and minimize external stimulations in order to ensure complete effect. Considering the conditions mentioned above, sedation may last minimum 30 minutes, but it may even last several hours, while muscle relaxation lasts 20-90 minutes and analgesia last 15-45 minutes. Analgesic effect occurs immediately after intravascular administration and within 5-10 minutes following intramuscular administration and this effect is most prominent in cattle.

Analgesia may not be sufficient in dogs and cats for interventions associated with severe pain. In such cases, combination with other preparations should be considered. Analgesia is usually limited in horses, but the degree may individually vary.

Warnings for cats and dogs

Intravenous administration of drug or fasting for 6-24 hours before drug is administered will significantly relieve nausea and vomiting. Intravascular administration should be slow. If required, administration can be repeated within 10-30 minutes following first administration in order to prolong effect. However, total dose given for prolonging the effect should not exceed recommended dose (3 mg/kg for dogs and 4 mg/kg for cats). Duration of effect is shorter, despite rapid onset, for intravenous administration.

If respiration arrest occurs for whatsoever reason, it is beneficial to compress on thoracic wall with two hands in rhythmic manner (artificial respiration) in order to restart respiration and restore to normal status.

Warnings for cattle and horse: Hypersensitivity to Sedinal 2% increases in physically challenged and tired animals as well as old and sick horses. Necessary precautions should be taken for tympania which may occur following administration of high dose in cattle and immobile animals.

It is recommended that higher dose is administered in hardly domesticated and nervous animals, while lower dose of Sedinal 2% is administered in old animals which suffers difficulty in breathing and are under stress.

ADVERSE / SIDE EFFECTS

For animals that were administered xylazine, blood pressure can transiently elevate followed by long-term decrease and deceleration of heart beats. Hyperglycemia, polyuria, thermoregulation disorder and irreversible local tissue irritations (rare) can be seen. Cardiac blockade, severe hypotension and gas distension secondary to air ingestion may occur particularly in dogs. Vomiting reflex is observed in cats and dogs before full sedation is ensured. Decreased ruminal activity leads to tympania and discharge of ruminal content in cattle; but, excessive salivation may be also observed.

DRUG INTERACTIONS

Dose should be decreased in concomitant use with barbiturates, opioids, anesthetics, tranquilizers and neuroleptics which depress central nervous system. Adrenalin administration following xylazine administration may lead to ventricular beat irregularities including ventricular fibrillation.

SYMPTOMS, PRECAUTIONS AND ANTIDOTE IN OVERDOSE

If overdose is accidentally administered, respiratory disorders, cardiac arrhythmias, epileptic symptoms and functional disorders can be seen. In such cases, alpha-2-receptor blockers such as yohimbine, atipamezole, 4-aminopyridine and pieroxin inhibit effects of xylazine. Analeptics (caffeine, amphetamine, picrotoxin, nikethamide) shorten duration of action of xylazine and deepen sedation.

WARNINGS FOR THE DRUG RESIDUES IN NUTRIENTS

Withholding Period (WHP): Drug residue elimination time is 0 day for meat and milk of cattle.

CONTRAINDICATIONS

It should not be used due to complications secondary to emetic effects in cases such as esophageal obstruction, gastric torsion and herniation. It should not be used in animals with urinary tract obstructions. It should not be used in animals with pulmonary and cardiac diseases and diabetes mellitus. Concomitant intravenous administration of sulphonamide + trimetoprim to animals which were administered xylazine for sedation may lead to lethal cardiac arrhythmia.

During pregnancy: xylazine is contraindicated in late periods of pregnancy since it may lead to premature labor or abortion.

PRECAUTIONS TO BE TAKEN BY ADMINISTRATOR AND WARNING FOR VETERINARY SURGEON

Animals that were sedated with xylazine may develop sudden defense reactions, such as kick and bite, against external stimulations. If the administrator accidentally self-administers the drug, a physician should be consulted with instructions for use. For preparations used in order to ensure combination, advices of manufacturer companies are valid.

GENERAL WARNINGS

Please refer to the veterinary surgeon before use and in case of an unexpected effect. Keep out of the reach of children.

STORAGE CONDITIONS AND SHELF LIFE

Keep at room temperature below 25°C away from exposure to sun light. After original package is opened, shelf life is 28 days should the preparation is stored at temperature below 25 C. Shelf life is 2 years from the date of production.

COMMERCIAL SUPPLY INDICATING COMPOSITION AND QUANTITY OF PACKAGING

It is supplied in 10 ml, 20 ml, 50 ml and 100 ml colorless glass vials within cardboard boxes.

SALE PLACE AND CONDITIONS

It is sold in the veterinary offices and the pharmacies with prescription written by veterinary surgeon (VP).

PROSPECTUS APPROVAL DATE: 12/02/2010

THE DATE AND THE NUMBER OF THE MINISTRY OF AGRICULTURE AND RURAL AFFAIRS LICENSE:

12.02.2010-22/029

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlık Ürünleri San. ve Tic. A.Ş

Dolayoba, Çınardere Mh. 3. Petek Sk. No: 18, 34896 Pendik-İSTANBUL

NAME AND ADDRESS OF MANUFACTURER COMPANY:

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