



Sedaxylan[®]

Keep it simple!

*'One sedative for cattle,
horses, dogs and cats'*

eurolab
Animal Health

Simple, reliable, Sedaxylan®

Introduction

Sedaxylan® is an injectable solution containing 20 mg xylazine base per ml.

Over the past 20 years, xylazine has proven to be a reliable sedative and premedicant in a wide range of animal species. Its sedative and analgesic activities are related to central nervous system (CNS) depression mediated by stimulation of α_2 -adrenoreceptors. Muscle relaxation is caused by inhibition of intraneural transmission within the CNS.

Indications

Sedaxylan® is used for restraint and to produce sedation to allow various diagnostic, dental, orthopedic or minor surgical procedures. In painful procedures, Sedaxylan® should always be used in combination with a local anaesthetic.

Sedaxylan® can also be used for sedation of animals in stressful situations like parturition or transport.

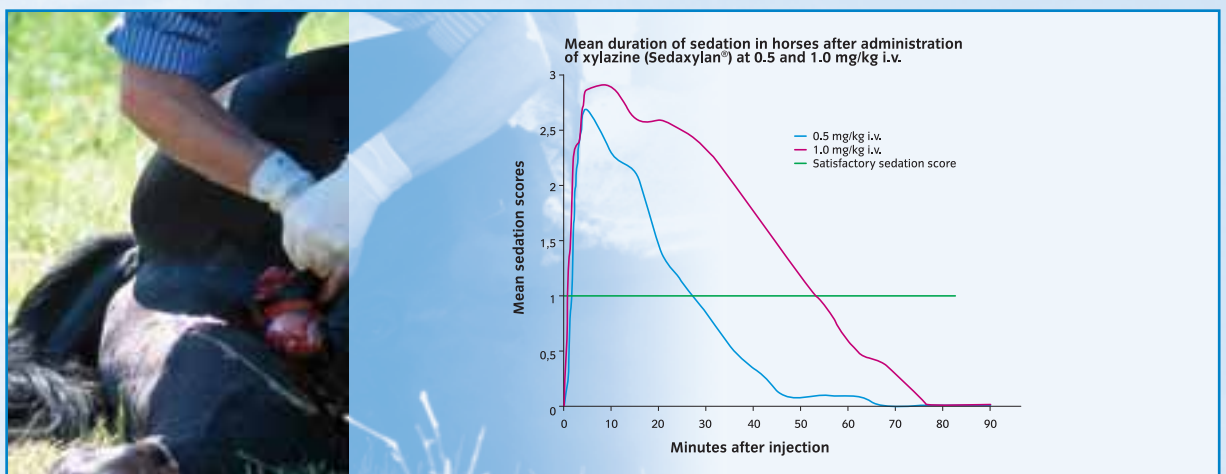
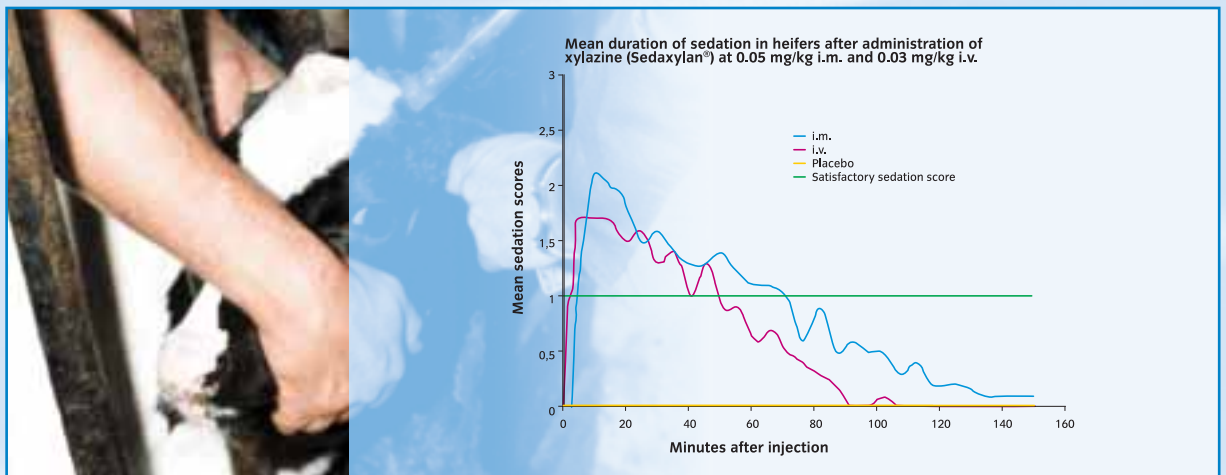
When Sedaxylan® is used as a preanaesthetic for general anaesthesia, the dose of barbiturate is decreased by one third to one half. Sedaxylan® decreases the halothane requirement MAC for anaesthesia by nearly 40%.

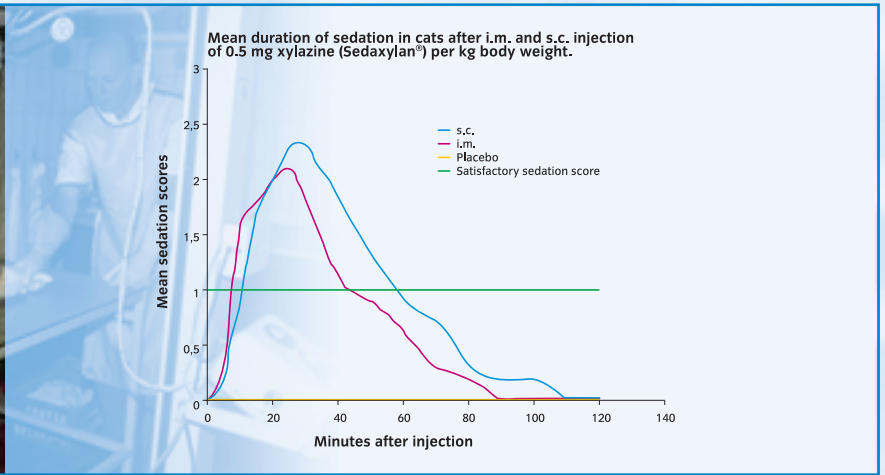
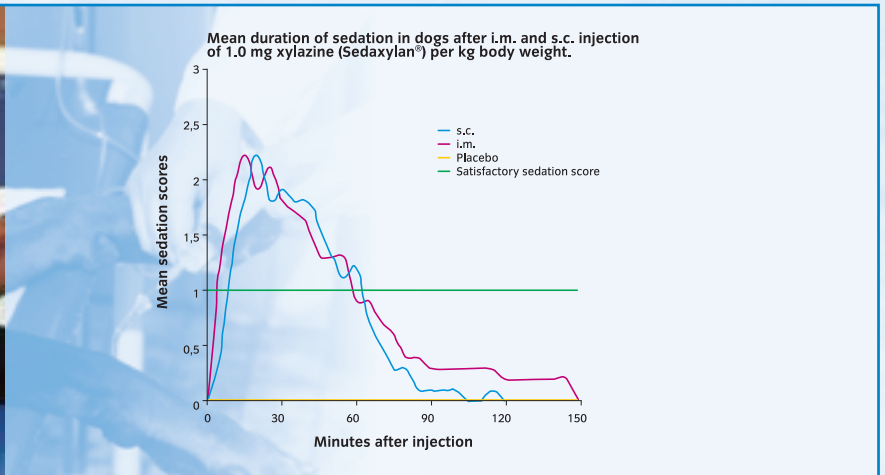
Highly effective, well tolerated

Major effects of Sedaxylan® on the CNS develop in approximately 10 to 15 minutes after intramuscular injection, and within 3 to 5 minutes following intravenous administration.

A dose-dependent sleep-like state is usually maintained for 1 to 2 hours. The duration of analgesia is only 15 to 30 minutes. Increasing the dose generally does not increase the degree of sedation but rather the duration of effect.

Results of clinical trials indicate that Sedaxylan® is highly effective in all target species. Local tolerance is very good. Systemic side effects are minimal and acceptable from a clinical point of view.





Dosage and administration

Species	Mode of administration	Xylazine dose (mg/kg)	Sedaxylan® dose
Cattle	IM	0.05 - 0.20	0.25 - 1.0 ml/100 kg
	IV	0.03 - 0.10	0.15 - 0.50 ml/100 kg
Horses	IV	0.5 - 1.0	2.5 - 5.0 ml/100 kg
Dogs	IM, SC	1.0 - 2.0	0.5 - 1.0 ml/10 kg
	IV	0.7 - 1.0	0.35 - 0.5 ml/10 kg
Cats	IM, SC	0.5 - 1.0	0.125 - 0.25 ml/5 kg

In the event of an accidental overdose, xylazine can be antagonized by the α_2 -adrenergic antagonist atipamezole, such as the Eurovet Animal Health BV product Atipam®.

The recommended dosage for atipamezole is:

- 0.03 mg/kg for cattle,
- 0.15 mg/kg for horses,
- 0.2 mg/kg for dogs and cats.

Withdrawal periods

Withdrawal period for meat of horses and cattle: as applicable in your country

Withdrawal period for milk: as applicable in your country

Shortened version of the insert

(for country specific details please consult your national registration)

Sedaxylan, 20 mg/ml solution for injection

Qualitative and quantitative composition:

Each millilitre contains:

Active substance:

Xylazine (base) 20.0 mg

Equivalent to 23.32 mg xylazine hydrochloride

Target species: Dogs, cats, horses and cattle.

Indications for use: Sedation of dogs, cats, horses and cattle.

Contra-indications:

Do not use in the later stages of pregnancy.

Do not use in animals with oesophageal obstruction, and torsion of the stomach, as the muscle relaxant properties of the drug appears to accentuate the effects of the obstruction and because of possible vomiting.

Do not use in animals with renal or hepatic impairment, respiratory dysfunction, cardiac abnormalities, hypotension and/or shock. Do not use in diabetic animals.

Do not use in calves younger than 1 week of age, foals younger than 2 weeks or in puppies and kittens younger than 6 weeks.

Undesirable effects:

In general, side effects, typical for an α_2 -adrenergic agonist, like bradycardia, reversible arrhythmia and hypotension can occur. Thermoregulation can be influenced and consequently body temperature can decrease or increase dependant on the ambient temperature. Depression of respiration and/or respiratory arrest can occur, especially in cats.

Cats and dogs

Cats and dogs frequently vomit during the onset of the xylazine-induced sedation, especially when the animals have just been fed. Animals may show profound salivation following an injection with xylazine.

Other adverse effects for dogs and cats include muscle tremors, bradycardia with AV-block, hypotension, reduced respiratory rate, movement in response to strong auditory stimuli, and increased urination in cats. In cats, xylazine causes uterine contractions and it may induce premature parturition.

In dogs, adverse effects are generally more pronounced after subcutaneous administration compared to intramuscular and the effect (efficacy) can be less predictable.

Cattle

In cattle xylazine may induce premature parturition, and it also reduces implantation of the ovum. Cattle, which have received high doses of xylazine sometimes suffer from loose faeces for 24 hours afterwards.

Other adverse reactions include profound salivation, ruminal atony, atony of the tongue, regurgitation, bloating, hypothermia, bradycardia, increased urination and reversible prolapse of the penis.

In cattle, adverse effects are generally more pronounced after intramuscular administration compared to intravenous.

Horses

Horses often sweat as the effects of the sedation are wearing off. Severe bradycardia and reduced respiratory rate have been reported especially in horses.

More frequent urination has been reported.

Muscle tremors and movement in response to sharp auditory or physical stimuli are possible. Although rare, violent reactions have been reported in horses following the administration of xylazine.

Ataxia and reversible prolapse of the penis may occur.

In very rare cases, xylazine may induce mild colic as the gut motility is depressed temporarily. As a preventative measure, the horse should receive no feed after sedation until the effect has faded completely.

Special precautions for use:

Older and exhausted animals are more sensitive to xylazine, whilst nervous or highly excitable animals may require a relative high dose. In case of dehydration, xylazine should be used cautiously.

Emesis is generally seen within 3-5 minutes after xylazine administration in cats and dogs. It is advisable to fast dogs and cats for 12 hours prior to surgery; they may have free access to drinking water.

Do not exceed the recommended dosage.

Following administration animals should be allowed to rest quietly until the full effect has been reached.

It is advised to cool animals when the ambient temperature is above 25°C and to keep animals warm at low temperatures.

Because the analgesic properties of xylazine are insufficient, in painful procedures xylazine should always be used in combination with a local or general analgesic!

Xylazine produces a certain degree of ataxia; therefore, xylazine must be used cautiously in procedures involving the distal extremities and in standing castrations in the horse.

Treated animals should be monitored until the effect has faded totally (e.g. cardiac and respiratory function, also in the post-operative phase).

For use in young animals, see the age restriction mentioned under 'Contra-indications'. If the product is intended to be used in young animals below these age limits, a benefit/risk assessment should be made by the veterinarian.

Amounts to be administered and administration route:

This product is intended for single intravenous, intramuscular or subcutaneous injection dependent upon the species in which it is to be used. The individual response to xylazine is somewhat varied (as with other sedatives), and depends partly on the dosage, the age of the patient, temperament of the patient, the surroundings (stress) and general condition (diseases, fat percentage, etc.). Doses also depend on the desired degree of sedation. Generally time to onset of sedation and recovery will take longer after intramuscular or subcutaneous injection at the recommended dosages than after intravenous injection. First effects are usually seen within 2 minutes following intravenous injection and within 5 to 10 minutes after intramuscular or subcutaneous injection. The maximum effect is seen 10 minutes later. It is generally seen that an increase in dose will lead to an increase of sedation, until maximum level is attained. Increasing the dosage beyond this point will lead to increase of the duration of the sedation. Recovery in calves may be prolonged after administration of 1.5 x the recommended dose. If the required depth of sedation is not achieved it is unlikely that repetition of the dose will prove more effective. In that case it is advisable to allow complete recovery repeating the procedure with a higher dose after 24 hours.

Accurately ascertain the body weight of an animal before treatment with xylazine.

Use a syringe with appropriate gradations.

Dogs:	1.0 - 2.0 mg	per kg body weight intramuscularly or subcutaneously
	0.5 - 1.0 ml	injection solution/10 kg body weight IM or SC
	0.7 - 1.0 mg	per kg body weight intravenously
	0.35 - 0.5 ml	injection solution/10 kg body weight IV
Cats:	0.5 - 1.0 mg	per kg body weight intramuscularly or subcutaneously
	0.125 - 0.25 ml	injection solution/5 kg body weight IM OR SC
Horses:	0.5 - 1.0 mg	per kg body weight intravenously
	2.5 - 5.0 ml	injection solution/100 kg body weight IV
Cattle:	0.05 - 0.20 mg	per kg body weight intramuscularly or
	0.25 - 1.0 ml	injection solution/100 kg body weight IM
	0.03 - 0.10 mg	per kg body weight intravenously
	0.15 - 0.5 ml	injection solution/100 kg body weight IV

The intravenous injection should be given slowly, especially in horses.

Withdrawal periods:

Horses (meat)	one day
Cattle (meat)	one day
Cattle (milk)	zero days

Shelf Life:

Shelf-life of the veterinary medicinal product as packaged for sale:

36 months

Shelf-life after first opening the container: 28 days



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