SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedaxylan 20 mg/ml solution for injection for dogs, cats, horses and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Xylazine 20.0 mg
Equivalent to 23.32 mg xylazine hydrochloride

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E 218)	1.0 mg
Propyl parahydroxybenzoate	0.1 mg
Citric acid monohydrate	
Sodium citrate	
Propylene glycol	
Water for injections	

Clear and colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats, horses and cattle.

3.2 Indications for use for each target species

Sedation of dogs, cats, horses and cattle.

3.3 Contraindications

Do not use in the later stages of pregnancy, see section 3.7

Do not use in animals with oesophageal obstruction, and torsion of the stomach, as the muscle relaxant properties of the veterinary medicinal product appear 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. See also section 3.7.

3.4 Special warnings

Dogs and cats:
Xylazine inhibits the normal intestinal motility. This may make xylazine sedation undesirable for upper gastro-intestinal radiographs because it promotes filling of the stomach with gas and makes interpretation less certain.
Brachycephalic dogs with air way disease or malfunction may develop life-threatening dyspnoea.

Horses:
Xylazine inhibits the normal intestinal motility. Therefore, it should only be used in horses with colic, that are not responsive to analgesics. The use of xylazine should be avoided in horses with caecal malfunction.
After treatment of horses with xylazine, the animals are reluctant to walk, so whenever possible the veterinary medicinal product should be administered in the place where the treatment/investigation is going to take place.
Caution should be taken in the administration of the veterinary medicinal product to horses susceptible to laminitis.
Horses with air way disease or malfunction may develop life-threatening dyspnoea.
The dose should be kept as low as possible.

Cattle:
Ruminants are highly susceptible to the effects of xylazine. Normally cattle remain standing at the lower doses, but some animals may lie down. At the highest recommended doses most animals will lie down and some animals may relapse in lateral recumbency.
Reticulo-ruminal motor functions are depressed after injection of xylazine. This may results in bloat. It is advisable to withhold feed and water for several hours before administration of xylazine.
In cattle the ability to eructate, cough and swallow is retained but reduced during the period of sedation, therefore cattle must be closely watched during the recovery period: the animals should be maintained in sternal recumbency.
In cattle life threatening effects may occur after intramuscular doses above 0.5 mg/kg body weight (respiratory and circulatory failure). Therefore very precise dosing is required.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Older and exhausted animals are more sensitive to xylazine, whilst nervous or highly excitable animals may require a relatively 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 in 3.3. If the veterinary medicinal product is intended to be used in young animals below these age-limits, a benefit-risk assessment should be made by the veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet or the label to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur.
Irritation, sensitisation, contact dermatitis and systemic effects cannot be excluded after skin contact.
Avoid skin contact and wear impermeable gloves when handling the veterinary medicinal product.
Wash the exposed skin immediately after exposure with large amounts of water.
In the case of accidental projection of the veterinary medicinal product into the eyes, rinse abundantly with fresh water. If irritation persists, seek the advice of a physician.
Remove contaminated clothes.
The veterinary medicinal product should not be administered by pregnant women.

To the physician:
Xylazine is an α-adrenoreceptor agonist whose toxicity may cause clinical effects including sedation, respiratory depression and coma, bradycardia and hypotension and hyperglycaemia. Ventricular arrhythmias have also been reported. Treatment should be supportive with appropriate intensive therapy.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[a], hypersalivation[b] Bradycardia[c], arrhythmia[d], hypotension Respiratory arrest, bradypnoea Muscle tremor, involuntary movement[e] Hypothermia[f]
Undetermined frequency (cannot be estimated from the available data)	Hyperthermia[f] Polyuria Uterine contraction, premature parturition

[a] During the onset of sedation, especially when the animals have just been fed.
[b] Profound.
[c] With AV-block.
[d] Reversible.
[e] In response to strong auditory stimuli.
[f] Thermoregulation can be influenced and consequently body temperature can decrease or increase dependant on the ambient temperature.

Dogs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[a] Bradycardia[b], hypotension Respiratory arrest, bradypnoea Muscle tremor Hypothermia[c], hyperthermia[c]
Undetermined frequency (cannot be estimated from the available data)	Hypersalivation[d] Arrhythmia[e] Involuntary movement[f]

[a] During the onset of sedation, especially when the animals have just been fed.
[b] With AV-block.
[c] Thermoregulation can be influenced and consequently body temperature can decrease or increase dependant on the ambient temperature.
[d] Profound.
[e] Reversible.
[f] In response to strong auditory stimuli.

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

Cattle

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bradycardia, arrhythmia[a], hypotension Hypothermia[b], hyperthermia[b] Respiratory arrest, respiratory depression Hypersalivation[c], tongue disorder[d], regurgitation, bloated
Undetermined frequency (cannot be estimated from the available data)	Penile prolapse[a] Loose stool[e], rumen atony Premature parturition, uterine disorder[f] Polyuria

[a] Reversible.
[b] Thermoregulation can be influenced and consequently body temperature can decrease or increase dependant on the ambient temperature.
[c] Profound.
[d] Atony.
[e] For 24 hours, in cattle which have received high doses of xylazine.
[f] Reduced implantation of the ovum.

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

Horses

Rare (1 to 10 animals / 10,000 animals treated):	Abnormal behaviour[a]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bradycardia[b], arrhythmia[c], hypotension Hyperthermia[d] Respiratory arrest Increased sweating[e] Muscle tremor[f], ataxia Colic[g, h], digestive tract hypomotility[h, i]
Undetermined frequency (cannot be estimated from the available data)	Penile prolapse[c] Hypothermia[d] Involuntary movement[f] Bradypnoea Frequent urination

[a] Violent reactions.
[b] Severe.
[c] Reversible.
[d] Thermoregulation can be influenced and consequently body temperature can decrease or increase dependant on the ambient temperature.
[e] As the effects of the sedation are wearing off.
[f] In response to sharp auditory or physical stimuli.
[g] Mild.

[h] To prevent this, horses should not consume any feed after sedation until the effect has completely subsided.
[i] Temporarily.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Although laboratory studies in rats have not shown any evidence of teratogenic or foetotoxic effects the use of the veterinary medicinal product during the first two trimesters of pregnancy should only be made according to the benefit-risk assessment by the responsible veterinarian.
Do not use in the later stages of pregnancy (particularly in cattle and cats), because xylazine causes uterine contractions and it may induce premature labour.

Fertility:
Do not use in cattle receiving ovum transplants as the increased uterine tone may reduce the chance of implantation of the ovum.

3.8 Interaction with other medicinal products and other forms of interaction

Other CNS depressant agents (barbiturates, narcotics, anaesthetics, tranquillizers, etc.) may cause additive CNS depression if used with xylazine. Dosages of these agents may need to be reduced. Xylazine should therefore be used cautiously in combination with neuroleptics or tranquillizers.

Xylazine should not be used in combination with sympathomimetic drugs such as epinephrine as ventricular arrhythmia may follow.

3.9 Administration routes and dosage

Dogs:	intramuscular, subcutaneous or intravenous use.
Cats:	intramuscular or subcutaneous use.
Horses:	intravenous use.
Cattle:	intramuscular or intravenous use.

This veterinary medicinal 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 in the level of sedation, until a 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.

To ensure a correct dosage, body weight should be determined as accurately as possible.
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In the event of an accidental overdose, cardiac arrhythmias, hypotension, and profound CNS and respiratory depression may occur. Seizures have also been reported after an overdose. Xylazine can be antagonized by α_2-adrenergic antagonists: atipamezole has been found to be a useful antidote in some cases. The recommended dosage is: 0.2 mg/kg for dogs and cats.

To treat the respiratory depressant effects of xylazine, mechanically respiratory support with or without respiratory stimulants (e.g. doxapram) can be recommended.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Horses:
Meat and offal: 1 day.

Cattle:
Meat and offal: 1 day.
Milk: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QN05CM92.

4.2 Pharmacodynamics

Xylazine belongs to the α_2-adrenoceptor agonists.
Xylazine is a α_2-adrenoceptor agonist, that acts by stimulation of central and peripheral α_2-adrenoceptors. Through its central stimulation of α_2-adrenoceptors, xylazine has potent antinociceptive activity. In addition, α_2-adrenergic activity, xylazine has α_1-adrenergic effects. Xylazine also produces skeletal muscle relaxation by inhibition of intraneuronal transmission of impulses at the central level of the central nervous system. The analgesic and skeletal muscle relaxation properties of xylazine show considerable interspecies variations. Sufficient analgesia generally will be attained in combination with other veterinary medicinal products only.

In many species, administration of xylazine produces a short-lived arterial pressor effect followed by a longer period of hypotension and bradycardia. These contrasting actions upon the arterial pressure apparently are related to the α_2- an α_1-adrenergic actions of xylazine.
Xylazine has several endocrine effects. Insulin (mediated by α_2-receptors in pancreatic β-cells which inhibit insulin release), ADH (decreased production of ADH, causing polyuria) and FSH (decreased) are reported to be influenced by xylazine.

4.3 Pharmacokinetics

Absorption (and action) is rapid following intramuscular injection. Levels of drug peak rapidly (usually within 15 minutes) and then decline exponentially. Xylazine is a highly lipid soluble organic base and diffuses extensively and rapidly (Vd 1.9-2.7). Within minutes after an intravenous injection, it can be found in a high concentration in the

kidneys, the liver, the CNS, the hypophyses, and the diaphragm. So there is a very rapid transfer from the blood vessels to the tissues. Intramuscular bioavailability is incomplete and variable ranging from 52-90% in the dog to 40-48% in the horse. Xylazine is metabolised extensively and eliminated rapidly (±70% via the urine, while the enteric elimination is ± 30%). The rapid elimination of xylazine is probably related to an extensive metabolism rather than to a rapid renal excretion of unchanged xylazine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Amber glass vial (type II) closed with a bromobutyl rubber stopper (type I) and oversealed with an aluminium cap in a cardboard box.

Pack sizes:
Cardboard box with 1 vial with 25 ml solution for injection.
Cardboard box with 1 vial with 50 ml solution for injection.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 16849/4001

8. DATE OF FIRST AUTHORISATION

04 July 2003

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

March 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 25 June 2025