PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARTON 25 / 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:

Active substance:
Xylazine (base) 20.0 mg,
equivalent to 23.32 mg xylazine hydrochloride

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

25, 50 ml

5. TARGET SPECIES

Dogs, cats, horses and cattle

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous, intramuscular or subcutaneous administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horse, cattle (meat and offal) - 1 day.
Cattle (milk) - 0 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Approved: 20 November 2014

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days
Once opened use by:

11. SPECIAL STORAGE CONDITIONS

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12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
Veterinary surgeon use only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, the Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

{Number allocated by MS}

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:

Active substance:
Xylazine (base) 20.0 mg, equivalent to 23.32 mg xylazine hydrochloride

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Dogs, cats, horses and cattle

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous, intramuscular or subcutaneous administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horse, cattle (meat and offal) - 1 day.
Cattle (milk) - 0 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days
Once opened use by:

11. SPECIAL STORAGE CONDITIONS

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12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
Veterinary surgeon use only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, the Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

{Number allocated by MS}

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

25 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains:

Active substance:
Xylazine (base) 20.0 mg, equivalent to 23.32 mg xylazine hydrochloride

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

25 ml

4. ROUTE(S) OF ADMINISTRATION

For intravenous, intramuscular or subcutaneous administration.

5. WITHDRAWAL PERIOD

Horse, cattle (meat and offal) - 1 day.
Cattle (milk) - 0 days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, the Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml solution for injection contains:
Active substance:
Xylazine (base) 20.0 mg
Equivalent to 23.32 mg xylazine hydrochloride

Excipients:
Methyl parahydroxybenzoate (E 218) 1.0 mg
Propyl parahydroxybenzoate 0.1 mg
Clear and colourless solution

4. INDICATION(S)

Sedation of dogs, cats, horses and cattle.

5. CONTRAINDICATIONS

Do not use in the later stages of pregnancy, see section 12: 'Special Warnings'.
Do not use in animals with oesophageal obstruction, and torsion of the stomach, as the muscle relaxant properties of the drug 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 12: 'Special Warnings': Use during pregnancy and lactation".

6. ADVERSE REACTIONS

In general, side effects, typical for an α2-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.
Dogs and cats

- Dogs and cats 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.

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 preventive measure the horse should receive no feed after sedation until the effect has faded completely.

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

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs, cats, horses and cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 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.

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*

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Horse (meat and offal) - 1 day.
Cattle (meat and offal) - 1 day.
Cattle (milk) - Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days

12. SPECIAL WARNING(S)

Special warnings for each target species

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 drug should be administered in the place where the treatment/investigation is going to take place.
- Caution should be taken in the administration of the 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.

Special precautions for use in animals
- 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 in section 5: 'Contraindications'. 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.

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 insert 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 product.
- Wash the exposed skin immediately after exposure with large amounts of water.
- In the case of accidental projection of the product into the eyes, rinse abundantly with fresh water. If irritation persists, seek the advice of a physician.
- Remove contaminated clothes.
- Pregnant women should not handle the product.
- ADVICE TO DOCTORS: 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.

Use during pregnancy and lactation
Although laboratory studies in rats have not shown any evidence of teratogenic or foetotoxic effects the use of the 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.
Do not use in cattle receiving ovum transplants as the increased uterine tone may reduce the chance of implantation of the ovum.

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.

Overdose (symptoms, emergency procedures, 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.

Incompatibilities
This veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2014

15. OTHER INFORMATION
Pack sizes: 25 or 50 ml.
Not all pack sizes may be marketed {National item}