PARTICULARS TO APPEAR ON THE OUTER PACKAGE - Cardboard box (10 ml, 5 x 10 ml, 25 ml, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Xylazine (as hydrochloride) 20 mg

3. PACKAGE SIZE

10 ml
25 ml
50 ml
5 x 10 ml

4. TARGET SPECIES

Cattle, horses, dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: IM
Horse: V
Dog: IM
Cat: IM

7. WITHDRAWAL PERIODS

Cattle: Meat: 1 day
Cattle: Milk: Zero hours
Horse: Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days. Use by:

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.
Accidental systemic exposure of pregnant women may result in uterine contractions and decreased foetal blood pressure. Pregnant users should handle the product with special caution to avoid accidental self-injection or ingestion.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 57446/5007

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS - 10 ml, 25 ml, 50 ml clear glass vial closed with a bromobutyl rubber stopper and aluminium cap

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xylamidor

Cattle, dogs, cats IM
Horses IV

Withdrawal periods:
Cattle: Meat: 1 day, Milk: Zero hours
Horses: Not to be used in horses intended for human consumption

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Xylazine 20 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by …

POM-V

10 ml
25 ml
50 ml

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance(s)
Xylazine (as hydrochloride) 20 mg

Excipient
Methyl parahydroxybenzoate (E218) 1.5 mg

Clear, colourless to almost colourless solution

3. Target species

Cattle, horses, dogs and cats.

4. Indications for use

Sedative with some analgesic and muscle relaxant properties for use in cattle, horses, dogs and cats in all cases where sedation is required including:

i) Handling fractious animals (e.g. for transportation).

ii) Medical examination e.g. x-ray examination, removal of bandages, examination of teats, penis and oral cavity.

iii) Pre-medication for minor superficial operations, painful manipulative procedures and local or regional anaesthesia.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use in the latter stages of pregnancy except at parturition.

In the cat and dog, because of the emetic effect which is sometimes produced, do not use xylazine in mechanical complications of the alimentary tract e.g. obstruction of the oesophagus, gastric torsion or hernia.

6. Special warnings

Special warnings:

Cattle

Tympany should be prevented in recumbent cattle by maintaining sternal recumbency.
For operations in lateral or dorsal recumbency, lower head and neck to prevent inhalation of ruminal contents.
Maintain recumbent and drowsy animals in the shade. In case of accidental overdosage leading to respiratory failure, cold water douches and artificial respiration are indicated.
After dose levels 3 and 4 cattle are likely to remain drowsy for several hours and should be kept in the shade.

Horses

Following intravenous injection in horses a transient rise and fall of blood pressure may be seen.
With horses the usual precautions required in handling should always be observed even when a high dose of xylazine has been given.

Dogs and cats

In cats and dogs if the stomach is full, vomiting occurs before sedation is complete.
The emetic effect is reduced by fasting for 6 to 24 hours.
Pre-medication with atropine in cats and dogs may reduce salivation and bradycardia effects.

Special precautions for safe use in the target species:

Caution is required when pulmonary disease is present.
Use with care in elderly or debilitated patients which may be adversely affected by profound cardiovascular changes.
When high doses are to be employed the animal should be fasted for some hours beforehand.
It must be noted that the swallowing reflex is reduced during the period when the action of the drug is at its peak.
Sedated animals should remain under observation until normal.
Segregate sedated animals.
Analeptics will shorten the period or reduce the depth of sedation.
Limited information available suggests that alpha-2 blockers such as atipamezole may be effective in reversing the sedation and other physiological effects of the drug.
Transient hyperglycaemia is a common finding after xylazine sedation.

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

To the user:

This product may be irritant to the skin, eyes and oral mucosa. Avoid skin, eye or mucosal contact. Wash the exposed skin immediately after exposure with large amounts of water. Remove contaminated clothes that are in direct contact with skin. In case of accidental contact of the product with eyes or oral mucosa rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

This product is a sedative. Care should be taken to avoid accidental self-injection. To avoid accidental self-injection, one of the following procedures should be adopted. Either use two sterile needles, one to fill syringe from bottle and one to inject patient, or once the required dose has been withdrawn from the vial, immediately remove the needle from the syringe, insert the needles into the injection site, and then connect the syringe to it. Used needles should be safely deposited in a closed container. In case of accidental oral intake or self-injection seek medical advice immediately and show the package leaflet or the label to the physician. DO NOT DRIVE as accidental self-injection or ingestion may result in sedation and changes in blood pressure.
If pregnant women handle the product, special caution should be exercised to avoid self-injection or ingestion. Accidental systemic exposure of pregnant women may result in uterine contractions and decreased foetal blood pressure.
Horses sedated with the product usually remain standing and may still kick.

To the physician:
Xylazine is an α2-adrenoreceptor agonist, symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.

Pregnancy and lactation:
Do not use in the latter stages of pregnancy except at parturition. As the safety of xylazine use during organogenesis has not been fully demonstrated by current methods it should be used with caution during the first month of pregnancy. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Concurrent administration of adrenoceptor stimulants is not recommended.
The concurrent intravenous use of potentiated sulphonamides with alpha-2 agonists has been reported to cause cardiac arrhythmias which may be fatal.
It is recommended that intravenous administration of Trimethoprim/Sulphonamide containing products should not be undertaken when horses have been sedated with xylazine.

Overdose:
Alpha$_2$-adrenoceptor blockers may reverse the effects.
In cattle, in case of accidental overdosage leading to respiratory failure, cold water douches and artificial respiration are indicated.

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

7. Adverse events

Not known.
Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first

instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Cattle: intramuscular use
Horses: intravenous use
Dogs: intramuscular use
Cats: intramuscular use

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

Cattle
This veterinary medicinal product is given by intramuscular injection. The dose rate is 0.05 - 0.3 mg/kg (0.25 - 1.5 ml per 100 kg) bodyweight, according to the degree of sedation required. Very fractious animals may require the higher dose rates not exceeding 0.3 mg/kg (Dose rate 4).

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 Sedation with a slight decrease of muscle tone. The ability to stand is maintained.

Dose 2 Sedation, marked decrease of muscle tone and some analgesia. The animal usually remains standing, but may lie down.

Dose 3 Deep sedation, further decrease of muscle tone and a degree of analgesia. The animal lies down.

Dose 4 Very deep sedation, a profound decrease in muscle tone and a degree of analgesia. The animal lies down.

Animals should not be disturbed until the drug has taken its full effect. The first effects are usually seen within 5 minutes of injection and the maximum effect is produced 10 minutes later. There is no struggling or excitement during induction or recovery.

If the required depth of sedation is not achieved, it is unlikely that repetition of the dose will prove more effective. It is advisable to allow complete recovery, repeating the procedure with a higher dose after 24 hours.
When any surgical treatment is carried out using xylazine, additional anaesthesia and analgesia should be considered.

Horses
Administer by slow intravenous injection, taking from one to two minutes to administer. Dosage depends on the degree of sedation required and the response of the animal and is 0.6 - 1 mg/kg bodyweight (3 - 5 ml/100 kg bodyweight). Nervous or highly excitable horses generally require the higher dose. Experience has shown that older horses and those that have undergone severe exertion before treatment respond more readily to xylazine.
Depending on the dosage, light to deep sedation with individually variable analgesia is obtained. The horse does not become recumbent.
Animals should not be disturbed until the drug has taken its full effect. This is usually obtained within 5 minutes of intravenous injection and lasts for approximately 20 minutes.
If the required depth of sedation is not achieved, it is unlikely that repetition of the dose will prove more effective. It is advisable to allow complete recovery, repeating the procedure with a higher dose rate, after 24 hours.
For operations and painful procedures, additional anaesthesia and analgesia should be considered.
Xylazine can also be administered to horses as a pre-medicant for operations on the recumbent animal using chloral hydrate, barbiturates, ketamine or halothane.

Cats
Administer intramuscularly at a dose rate of 3 mg/kg (0.15 ml/kg) bodyweight.
The effect is adequate for procedures that are not associated with any considerable degree of pain. Pre-medication with atropine is advantageous.
When used in conjunction with ketamine, xylazine pre-medication eliminates muscular stiffness during anaesthesia and maintains sedation throughout the recovery period.
Barbiturate anaesthesia should not be induced until sedation is at its deepest, i.e. about 20 minutes after administration of xylazine. Under these conditions the dose of barbiturates is reduced by about half.

Dogs
Administer by intramuscular injection at a dose rate of 1 - 3 mg/kg (0.05 - 0.15 ml/kg) bodyweight. Good sedation is usually achieved at the lower end of the dose range given above, but excitable or vicious animals require a higher dose. The effect is adequate for procedures that are not associated with any considerable degree of pain.
For painful procedures, additional anaesthesia and analgesia should be considered. Pre-medication with atropine may be advantageous.
When used for pre-anaesthetic medication, xylazine reduces the dose required in the case of barbiturates by about half. Xylazine can also be used as a pre-medicant for ketamine induced anaesthesia.

The closure should not be punctured more than 25 times

9. Advice on correct administration

Read the user warnings before using this product.

10. Withdrawal periods

Animals must not be slaughtered for human consumption during treatment.

Cattle: Meat: 1 day.
Cattle: Milk: Zero hours.

Horse: Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
Shelf life after first opening the immediate packaging: 28 days.
Once the vial is broached, using the shelf-life after first opening, calculate the discard date and record in the space provided on the label.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 57446/5007

Package sizes:
10 ml, 25 ml, 50 ml or 5 x 10 ml vials in a cardboard box.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria
Tel: +43 (0)664 8455326
E-mail: adverse.events@vetviva.com

17. Other information

POM-V

Gavin Hall

Approved: 01 September 2025