[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Xylazine (as hydrochloride) 20 mg

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 (E218)	1.5 mg
Sodium chloride	
Sodium hydrogen carbonate (for pH adjustment)	
Water for injections	

Clear, colourless to almost colourless solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, dogs, cats

3.2 Indications for use for each target species

Cattle
For sedation, muscle relaxation and analgesia for minor surgery.
In combination with other substances for anaesthesia.

Horses
For sedation and muscle relaxation.
In combination with other substances for analgesia and anaesthesia.

Dogs, cats
For sedation.
In combination with other substances for analgesia, anaesthesia and muscle relaxation.

3.3 Contraindications

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with gastrointestinal obstruction, as it is a muscle relaxant and the properties of the veterinary medicinal product appear to enhance the effects of an obstruction, and because of the risk of vomiting.
Do not use in cases of pulmonary disease (breathing deficiency) or cardiac disorders (especially in cases of ventricular arrhythmia).
Do not use in cases of impaired liver or renal function.

Do not use in cases of predetermined history of seizures.
Do not use in cases of hypotension and shock.
Do not use in animals with diabetes mellitus.
Do not administer simultaneously with sympathomimetic amines (e.g. epinephrine).
Do not use in calves less than 1 week of age, foals less than 2 weeks of age or puppies and kittens under 6 weeks of age.
Do not use during the last stage of pregnancy (danger of premature birth), except at parturition (see section 3.7).

3.4 Special warnings

In septicaemic diseases, in conditions of severe anaemia, the therapeutic index is decreased.

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 airway disease or malfunction may develop life-threatening dyspnoea.
The dose should be kept as low as possible.
The combination with other pre-anaesthetic agents or anaesthetic agents should be the subject of a benefit/risk assessment. This assessment should consider the composition of the products, their dose and the nature of the surgery. Recommended dosages are likely to vary according to the choice of the anaesthetic combination.

Dogs, cats
Xylazine inhibits 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 airway disease or malfunction may develop life-threatening dyspnoea.
The combination with other pre-anaesthetic agents or anaesthetic agents should be the subject of a benefit/risk assessment. This assessment should consider the composition of the products, their dose and the nature of the surgery. Recommended dosages are likely to vary according to the choice of the anaesthetic combination.

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 lapse into lateral recumbency.
Reticulo-ruminal motor functions are depressed after injection of xylazine. This may result in bloat. It is advisable to withhold feed and water in adult cattle for several hours before administration of xylazine. Fasting in calves might be indicated but should only be done at the discretion of a benefit/risk assessment made by the responsible veterinarian.
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.
The combination with other pre-anaesthetic agents or anaesthetic agents should be the subject of a benefit/risk assessment. This assessment should consider the composition of the products, their dose and the nature of the surgery. Recommended dosages are likely to vary according to the choice of the anaesthetic combination.

3.5 Special precautions for use

Special precautions for safe use in the target species:

If premedication with other agents (e.g. sedative/analgesic premedication) was given prior to the use of xylazine, the xylazine dose should be reduced.
Keep the animals calm, because they may respond to external stimuli.
Avoid intra-arterial administration.
Tympany may occasionally occur in recumbent cattle and can be avoided by maintaining the animal in sternal recumbency.
To avoid aspiration of saliva or food, lower the animal's head and neck. Fast the animals before use of the product.
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.
Pre-medication with atropine in cats and dogs may reduce salivation and bradycardia effects.
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.
For painful procedures, xylazine should always be used in combination with local or general anaesthesia.
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. When manipulating horses' hindquarters, defensive movements should be expected, despite sedation.
Treated animals should be monitored until the effect has faded totally (e.g. cardiac and respiratory function, also in the post-operative phase) and should be segregated to avoid bullying.
For use in young animals, see the age restriction mentioned in section 3.3. 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:

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. 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.
Methyl parahydroxybenzoate can cause hypersensitivity reactions. People with a known hypersensitivity to the active substance, parabens or any of the excipients should avoid contact with the product.

To the physician:
Xylazine is an α_2-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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data):	Uterine contraction, Uterine disorder (reduced implantation of ovum), Penile prolapse (reversible); Hypersalivation, Decreased ruminal activity (inhibition of rumen motility), Digestive tract tympany, Regurgitation, Loose stool[1]; Tongue paralysis; Respiratory depression, Respiratory arrest; Hypotension, Bradycardia, Arrhythmia; Decreased body temperature (only after an increase in temperature); Excitation (paradoxical excitation reactions); Hyperglycaemia; Polyuria; Application site irritation (reversible local tissue irritation).

[1]For 24 hours after high doses of xylazine.

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Colic[2]
Undetermined frequency (cannot be estimated from the available data):	Uterine contraction, Penile prolapse (reversible); Respiratory depression, Respiratory arrest; Hypotension, Bradycardia, Arrhythmia; Decreased body temperature; Excitation (paradoxical excitation reactions)[3]; Muscle tremor[3]; Hyperglycaemia; Polyuria; Application site irritation (reversible local tissue irritation); Increased sweating[4].

[2]Mild colic may occur after the use of substances with α_2-sympathomimetic activity since the intestinal motility is temporarily inhibited by the active substances of this substance class. To prevent this, horses should not consume any feed after sedation until the effect has completely subsided.

[3]In response to sharp auditory or physical stimuli. Although rare, violent reactions have been reported in horses following the administration of xylazine.
[4]As the effects of the sedation are wearing off.

Dogs, cats:

Rare (1 to 10 animals / 10,000 animals treated):	Gastric bloat[5]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Cardiac arrest, Hypotension;[6] Dyspnoea, Bradypnea, Pulmonary oedema;[6] Seizure, Prostration, Pupil disorder, Tremor.[6]
Undetermined frequency (cannot be estimated from the available data):	Respiratory depression, Respiratory arrest (particularly in cats); Bradycardia, Arrhythmia; Decreased body temperature; Excitation (paradoxical excitation reactions); Hyperglycaemia; Polyuria; Application site irritation (reversible local tissue irritation); Hypersalivation, Vomiting[7]; Uterine contraction (cats).

[5]In susceptible dog breeds with a large chest (Great Dane, Irish Setter).
[6]In anaesthetized animals, mainly during and after the recovery period.
[7]During the onset of the xylazine-induced sedation, especially when the animals have just been fed.

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 section 'contact details' of the package leaflet.

3.7 Use during pregnancy, lactation or lay

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) except at parturition, 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.

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 concomitantly with sympathomimetic drugs such as epinephrine, as ventricular arrhythmia may follow.

The concurrent intravenous use of potentiated sulphonamides with alpha-2 agonists has been reported to cause cardiac arrhythmias which may be fatal. Whilst no such effects have been reported with this product, it is recommended that intravenous administration of Trimethoprim/Sulphonamide containing products should not be undertaken when horses have been sedated with xylazine.

3.9 Administration routes and dosage

For intravenous, intramuscular or subcutaneous use.

Cattle: intravenous or intramuscular
Horses: intravenous
Dogs: intravenous or intramuscular
Cats: intramuscular or subcutaneous

To ensure a correct dosage, body weight (bw) should be determined as accurately as possible. The intravenous injection should be given slowly, especially in horses.

CATTLE

Intravenous use

In case of intravenous use, the dose recommended for intramuscular administration is reduced to 1/2 to 1/3, according to the individual reaction of the animal. The onset of effect is accelerated through intravenous administration, whereas the duration of effect is normally shortened.

Dose level	Xylazine (mg/kg bw)	Xylamidor (ml/100 kg bw)	Xylamidor (ml/500 kg bw)
I	0.016 - 0.024	0.08 - 0.12	0.4 - 0.6
II	0.034 - 0.05	0.18 - 0.25	0.85 - 1.25
III	0.066 - 0.10	0.33 - 0.5	1.65 - 2.5

Intramuscular use

Dose level	Xylazine (mg/kg bw)	Xylamidor (ml/100 kg bw)	Xylamidor (ml/500 kg bw)
I	0.05	0.25	1.25
II	0.1	0.5	2.5
III	0.2	1.0	5.0
IV	0.3	1.5	7.5

If necessary, the effect can be amplified or prolonged by a second administration. To amplify the effect, an additional dose may be administered 20 minutes after the first administration. To prolong the effect, an additional dose may be administered 30 – 40 minutes after the first administration. However, the total dose administered should not exceed Dose level IV.

Dosage I: Sedation with slight reduction of muscle tone. The cattle are still able to stand.

Dosage II: Sedation with pronounced reduction of the muscle tone and slight analgesia. The cattle mostly remain able to stand but may also lie down.

Dosage III: Deep sedation, further reduction in muscle tone, partial analgesia. The cattle lie down (prior withholding of feed is recommended).

Dosage IV: Very deep sedation with a pronounced reduction in the muscle tone, partial analgesia. The cattle lie down.

HORSES

For sedation:
0.6 - 1.0 mg xylazine/kg bw intravenously (corresponding to 3 - 5 ml per 100 kg bw)**.**

Depending on the dose, light to deep sedation with individually variable analgesia and profound decrease in muscle tone is obtained. Generally, the horse does not become recumbent;

For induction of anaesthesia in combination with ketamine:
1 mg xylazine/kg bw intravenously (corresponding to 5 ml per 100 kg bw) and after onset of deep sedation, 2 mg ketamine/kg bw intravenously.

If definite muscle relaxation is also necessary, muscle relaxants may be administered to the recumbent animal until the first signs of adequate relaxation occur.

DOGS

For sedation:
1 mg xylazine/kg bw intravenously (corresponding to 0.5 ml per 10 kg bw).
1 to 3 mg xylazine/kg bw intramuscularly (corresponding to 0.5 to 1.5 ml per 10 kg bw).

For induction of anaesthesia in combination with ketamine:
2 mg xylazine/kg bw intramuscularly (corresponding to 1 ml per 10 kg bw) and 6 - 10 mg ketamine/kg bw intramuscularly.

Very often the administration of the product causes vomiting in dogs. This effect, if unwanted, can be mitigated by fasting.

CATS

For sedation:
2 mg xylazine/kg bw intramuscularly (corresponding to 0.1 ml per kg bw).
2 to 4 mg xylazine/kg bw subcutaneously (corresponding to 0.1 to 0.2 ml per kg bw).

For induction of anaesthesia in combination with ketamine:
2 mg xylazine/kg bw intramuscularly (corresponding to 0.1 ml per kg bw) and 5 - 15 mg ketamine/kg bw intramuscularly.

Very often the administration of the product causes vomiting in cats. This effect, if unwanted, can be mitigated by fasting.

The rubber stopper may be safely punctured up to 25 times.

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

In cases of accidental overdose, cardiac arrhythmia, hypotension, severe CNS and respiratory depression as well as seizures may occur. Xylazine can be antagonised by α2-adrenergic antagonists.

To treat the respiratory depressant effects of xylazine, mechanical 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

3.12 Withdrawal periods

Cattle, horse:
Meat and offal: 1 day
Milk: zero hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN05CM92

4.2 Pharmacodynamics

Xylazine is a thiazine derivative with a sedative, hypnotic, local anaesthetic and hypotensive effect. Depending on the animal species, it also demonstrates analgesic as well as muscle-relaxing properties. However, sufficient analgesia generally will be attained in combination with other products only.
It is an agonist of the α_2-adrenergic receptor and acts on the presynaptic and postsynaptic receptors of the central and peripheral nervous system.
Similar to clonidine, the sedation and analgesia can be explained by stimulation of the central α_2-adrenergic receptor. Parts of the adverse effects observed appear to be based on the same mechanism of action.

4.3 Pharmacokinetics

Xylazine is quickly absorbed and distributed in the animal. Independent of the animal species, the maximum plasma level is reached within 12 - 14 minutes after intravenous injection. By contrast, the bioavailability after intramuscular administration depends on the animal species.
Xylazine is quickly and completely broken down into various metabolites. After intramuscular and intravenous administration, the half-life for elimination is 23 - 60 minutes. The half-life for complete elimination, independent of the type of administration or dosage, is 2 - 3 hours. In a residue test in cattle with radioactively labelled active substance, 85 % of the radioactivity administered is eliminated via the urine 24 hours after IV administration.

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: 21 months

Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

This medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Clear glass vial type I with 10 ml solution for injection or clear glass vial type II with 25 ml or 50 ml solution for injection, closed with a coated bromobutyl rubber stopper, type I and aluminium cap.

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.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

VetViva Richter GmbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

2. STATEMENT OF ACTIVE SUBSTANCES

Xylazine (as hydrochloride) 20 mg/ml

3. PACKAGE SIZE

10 ml
25 ml
50 ml
5 x 10 ml

4. TARGET SPECIES

Cattle, horses, dogs, cats

5. INDICATIONS

-

6. ROUTES OF ADMINISTRATION

Cattle: IV, IM
Horse: IV
Dog: IV, IM
Cat: IM, SC

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle, horse:
Meat and offal: 1 day
Milk: zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

-

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

Read the package leaflet before use.

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

14. MARKETING AUTHORISATION NUMBERS

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, horses, dogs, cats

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 …

B. 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:
Xylazine (as hydrochloride) 20 mg

Excipients:
Methyl parahydroxybenzoate (E218) 1.5 mg

Clear, colourless to almost colourless solution for injection.

3. Target species

Cattle, horses, dogs, cats

4. Indications for use

Cattle
For sedation, muscle relaxation and analgesia for minor surgery.
In combination with other substances for anaesthesia.

Horses
For sedation and muscle relaxation.
In combination with other substances for analgesia and anaesthesia.

Dogs, cats
For sedation.
In combination with other substances for analgesia, anaesthesia and muscle relaxation.

5. Contraindications

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with gastrointestinal obstruction, as it is a muscle relaxant and the properties of the veterinary medicinal product appear to enhance the effects of an obstruction, and because of the risk of vomiting.
Do not use in cases of pulmonary disease (breathing deficiency) or cardiac disorders (especially in cases of ventricular arrhythmia).
Do not use in cases of impaired liver or renal function.
Do not use in cases of predetermined history of seizures.
Do not use in cases of hypotension and shock.
Do not use in animals with diabetes mellitus.
Do not administer simultaneously with sympathomimetic amines (e.g. epinephrine).
Do not use in calves less than 1 week of age, foals less than 2 weeks of age or puppies and kittens under 6 weeks of age.
Do not use during the last stage of pregnancy (danger of premature birth), except at parturition (see section “Special warnings”).

6. Special warnings

Special warnings:
In septicaemic diseases, in conditions of severe anaemia, the therapeutic index is decreased.

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 airway disease or malfunction may develop life-threatening dyspnoea.
The dose should be kept as low as possible.
The combination with other pre-anaesthetic agents or anaesthetic agents should be the subject of a benefit/risk assessment. This assessment should consider the composition of the products, their dose and the nature of the surgery. Recommended dosages are likely to vary according to the choice of the anaesthetic combination.

Dogs, cats
Xylazine inhibits 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 airway disease or malfunction may develop life-threatening dyspnoea.
The combination with other pre-anaesthetic agents or anaesthetic agents should be the subject of a benefit/risk assessment. This assessment should consider the composition of the products, their dose and the nature of the surgery. Recommended dosages are likely to vary according to the choice of the anaesthetic combination.

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 lapse into lateral recumbency.
Reticulo-ruminal motor functions are depressed after injection of xylazine. This may result in bloat. It is advisable to withhold feed and water in adult cattle for several hours before administration of xylazine. Fasting in calves might be indicated but should only be done at the discretion of a benefit/risk assessment made by the responsible veterinarian.
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.
The combination with other pre-anaesthetic agents or anaesthetic agents should be the subject of a benefit/risk assessment. This assessment should consider the composition of the products, their dose and the nature of the surgery. Recommended dosages are likely to vary according to the choice of the anaesthetic combination.

Special precautions for safe use in the target species:
If premedication with other agents (e.g. sedative/analgesic premedication) was given prior to the use of xylazine, the xylazine dose should be reduced.
Keep the animals calm, because they may respond to external stimuli.
Avoid intra-arterial administration.
Tympany may occasionally occur in recumbent cattle and can be avoided by maintaining the animal in sternal recumbency.

To avoid aspiration of saliva or food, lower the animal's head and neck. Fast the animals before use of the product.
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.
Pre-medication with atropine in cats and dogs may reduce salivation and bradycardia effects.
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.
For painful procedures, xylazine should always be used in combination with local or general anaesthesia.
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. When manipulating horses' hindquarters, defensive movements should be expected, despite sedation.
Treated animals should be monitored until the effect has faded totally (e.g. cardiac and respiratory function, also in the post-operative phase) and should be segregated to avoid bullying.
For use in young animals, see the age restriction mentioned in section "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:
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. 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.
Methyl parahydroxybenzoate can cause hypersensitivity reactions. People with a known hypersensitivity to the active substance, parabens or any of the excipients should avoid contact with the product.

To the physician:
Xylazine is an α_2-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:
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) except at parturition, 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 concomitantly with sympathomimetic drugs such as epinephrine, as ventricular arrhythmia may follow.
The concurrent intravenous use of potentiated sulphonamides with alpha-2 agonists has been reported to cause cardiac arrhythmias which may be fatal. Whilst no such effects have been reported with this product, it is recommended that intravenous administration of Trimethoprim/Sulphonamide containing products should not be undertaken when horses have been sedated with xylazine.

Overdose:
In cases of accidental overdose, cardiac arrhythmia, hypotension, severe CNS and respiratory depression as well as seizures may occur. Xylazine can be antagonised by α2-adrenergic antagonists. To treat the respiratory depressant effects of xylazine, mechanical respiratory support with or without respiratory stimulants (e.g. doxapram) can be recommended.

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

7. Adverse events

Cattle:
Undetermined frequency (cannot be estimated from the available data):
Uterine contraction, uterine disorder (reduced implantation of ovum), penile prolapse (reversible), hypersalivation, decreased ruminal activity (inhibition of rumen motility), digestive tract tympany, regurgitation, loose stool[1], tongue paralysis, respiratory depression, respiratory arrest, hypotension, bradycardia, arrhythmia, decreased body temperature (only after an increase in temperature), excitation (paradoxical excitation reactions), hyperglycaemia, polyuria, application site irritation (reversible local tissue irritation).

[1]For 24 hours after high doses of xylazine.

Horses:
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Colic[2]

Undetermined frequency (cannot be estimated from the available data):
Uterine contraction, penile prolapse (reversible), respiratory depression, respiratory arrest, hypotension, bradycardia, arrhythmia, decreased body temperature, excitation (paradoxical excitation reactions)[3], muscle tremor[3], hyperglycaemia, polyuria, application site irritation (reversible local tissue irritation), increased sweating[4].

[2]Mild colic may occur after the use of substances with α_2-sympathomimetic activity since the intestinal motility is temporarily inhibited by the active substances of this substance class. To prevent this, horses should not consume any feed after sedation until the effect has completely subsided.
[3]In response to sharp auditory or physical stimuli. Although rare, violent reactions have been reported in horses following the administration of xylazine.
[4]As the effects of the sedation are wearing off.

Dogs, cats:
Rare (1 to 10 animals / 10,000 animals treated):
Gastric bloat[5]

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Cardiac arrest, hypotension, dyspnoea, bradypnea, pulmonary oedema, seizure, prostration, pupil disorder, tremor.[6]

Undetermined frequency (cannot be estimated from the available data):
Respiratory depression, respiratory arrest (particularly in cats), bradycardia, arrhythmia, decreased body temperature, excitation (paradoxical excitation reactions), hyperglycaemia, polyuria, application site irritation (reversible local tissue irritation), hypersalivation, vomiting[7], uterine contraction (cats).

[5]In susceptible dog breeds with a large chest (Great Dane, Irish Setter).
[6]In anaesthetized animals, mainly during and after the recovery period.
[7]During the onset of the xylazine-induced sedation, especially when the animals have just been fed.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

For intravenous, intramuscular or subcutaneous use.

Cattle: intravenous or intramuscular
Horses: intravenous
Dogs: intravenous or intramuscular
Cats: intramuscular or subcutaneous

To ensure a correct dosage, body weight (bw) should be determined as accurately as possible. The intravenous injection should be given slowly, especially in horses.

CATTLE

Intravenous use

In case of intravenous use, the dose recommended for intramuscular administration is reduced to 1/2 to 1/3, according to the individual reaction of the animal. The onset of effect is accelerated through intravenous administration, whereas the duration of effect is normally shortened.

Dose level	Xylazine (mg/kg bw)	Xylamidor (ml/100 kg bw)	Xylamidor (ml/500 kg bw)
I	0.016 - 0.024	0.08 - 0.12	0.4 - 0.6
II	0.034 - 0.05	0.18 - 0.25	0.85 - 1.25
III	0.066 - 0.10	0.33 - 0.5	1.65 - 2.5

Intramuscular use

Dose level	Xylazine (mg/kg bw)	Xylamidor (ml/100 kg bw)	Xylamidor (ml/500 kg bw)
I	0.05	0.25	1.25

II	0.1	0.5	2.5
III	0.2	1.0	5.0
IV	0.3	1.5	7.5

If necessary, the effect can be amplified or prolonged by a second administration. To amplify the effect, an additional dose may be administered 20 minutes after the first administration. To prolong the effect, an additional dose may be administered 30 – 40 minutes after the first administration. However, the total dose administered should not exceed Dose level IV.

Dosage I: Sedation with slight reduction of muscle tone. The cattle are still able to stand.

Dosage II: Sedation with pronounced reduction of the muscle tone and slight analgesia. The cattle mostly remain able to stand but may also lie down.

Dosage III: Deep sedation, further reduction in muscle tone, partial analgesia. The cattle lie down (prior withholding of feed is recommended).

Dosage IV: Very deep sedation with a pronounced reduction in the muscle tone, partial analgesia. The cattle lie down.

HORSES

For sedation:
0.6 - 1.0 mg xylazine/kg bw intravenously (corresponding to 3 - 5 ml per 100 kg bw)**.**

Depending on the dose, light to deep sedation with individually variable analgesia and profound decrease in muscle tone is obtained. Generally, the horse does not become recumbent.

For induction of anaesthesia in combination with ketamine:
1 mg xylazine/kg bw intravenously (corresponding to 5 ml per 100 kg bw) and after onset of deep sedation, 2 mg ketamine/kg bw intravenously.

If definite muscle relaxation is also necessary, muscle relaxants may be administered to the recumbent animal until the first signs of adequate relaxation occur.

DOGS

For sedation:
1 mg xylazine/kg bw intravenously (corresponding to 0.5 ml per 10 kg bw).
1 to 3 mg xylazine/kg bw intramuscularly (corresponding to 0.5 to 1.5 ml per 10 kg bw).

For induction of anaesthesia in combination with ketamine:
2 mg xylazine/kg bw intramuscularly (corresponding to 1 ml per 10 kg bw) and 6 - 10 mg ketamine/kg bw intramuscularly.

Very often the administration of the product causes vomiting in dogs. This effect, if unwanted, can be mitigated by fasting.

CATS

For sedation:
2 mg xylazine/kg bw intramuscularly (corresponding to 0.1 ml per kg bw).
2 to 4 mg xylazine/kg bw subcutaneously (corresponding to 0.1 to 0.2 ml per kg bw).

For induction of anaesthesia in combination with ketamine:
2 mg xylazine/kg bw intramuscularly (corresponding to 0.1 ml per kg bw) and 5 - 15 mg ketamine/kg bw intramuscularly.

Very often the administration of the product causes vomiting in cats. This effect, if unwanted, can be mitigated by fasting.

The rubber stopper may be safely punctured up to 25 times.

9. Advice on correct administration

See section: Dosage for each species, routes and method of administration

10. Withdrawal periods

Cattle, horse:
Meat and offal: 1 day
Milk: zero hours

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

12. Special precautions for disposal

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 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

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. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder, manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

<Local representatives and contact details to report suspected adverse reactions>:

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

<17. Other information>