PARTICULARS TO APPEAR ON THE OUTER PACKAGE {OUTER CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nerfasin 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Xylazine 100 mg (equivalent to 116.55 mg xylazine hydrochloride).

3. PACKAGE SIZE

10 ml
25 ml
50 ml

4. TARGET SPECIES

Cattle (≥ 200 kg) and horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: intramuscular use.
Horses: intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the vial: 28 days.
Once broached, use by…..

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.

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

Le Vet B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 19994/4018

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{VIAL LABEL 10 ml, 25 ml or 50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nerfasin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Xylazine 100 mg/ml (equivalent to 116.55 mg/ml xylazine hydrochloride).

10 ml
25 ml
50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nerfasin 100 mg/ml solution for injection for cattle and horses

2. Composition

Each ml contains:

Active substance:
Xylazine: 100 mg
(equivalent to 116.55 mg xylazine hydrochloride)

Excipients:
Methyl parahydroxybenzoate (E218) 1.0 mg

Clear, colourless solution.

3. Target species

Cattle (≥ 200 kg) and horses.

4. Indications for use

Sedation.
Premedication in combination with an anaesthetic.
See also section “Contraindications”.

5. Contraindications

- Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
- Do not use in animals with gastrointestinal obstruction 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 severe renal or hepatic impairment, respiratory dysfunction, cardiac abnormalities, hypotension and/or shock.
- Do not use in diabetic animals.
- Do not use in animals with a history of seizures.
- Do not use in cattle with a body weight of less than 200 kg. Do not use in foals younger than 2 weeks.
- Do not use during the last stage of pregnancy (danger of premature birth), except at parturition (see section “Pregnancy and lactation”).

6. Special warnings

Special warnings:

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 airway disease or malfunction may develop life-threatening dyspnoea.
- The dose should be kept as low as possible.
- The association 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 veterinary medicinal products, their dose and the nature of the surgery. Recommended dosages are likely to vary according to the choice of the anaesthetic association.

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 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.
- This veterinary medicinal product should only be used in cattle weighing 200 kg or more. Since it is highly concentrated, a slight deviation from the actual volume to be injected may cause serious adverse reactions. In case cattle weighing less than 200 kg need to be treated, xylazine with a lower strength should be used (e.g. 20 mg/ml).

- The association 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 veterinary medicinal products, their dose and the nature of the surgery. Recommended dosages are likely to vary according to the choice of the anaesthetic association.

Special precautions for safe use in the target species:

- 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 veterinary medicinal 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.
- 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.
- 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.

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

- 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 but DO NOT DRIVE as sedation and changes in blood pressure may occur.
- 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 veterinary medicinal product with eyes, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

- If pregnant women handle the veterinary medicinal product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

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:
Laboratory studies in rats have not produced 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) 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 in combination 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 veterinary medicinal product, it is recommended that intravenous administration of trimethoprim/sulphonamide containing veterinary medicinal products should not be undertaken when horses have been sedated with xylazine.

Overdose:
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 α2-adrenergic antagonists.

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

Special restrictions for use and special conditions for use:

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:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bradycardia (slow heart rate), arrhythmia (irregular heartbeat)[a], hypotension (low blood pressure) Hypothermia (low body temperature)[b], hyperthermia (high body temperature)[b] Respiratory depression, respiratory arrest, stridor (nasal-noisy breathing) Hypersalivation (profound-increased salivation), tongue disorder[c], regurgitation, bloated
Undetermined frequency (cannot be estimated from the available data):	Penile prolapse[a] Loose stool[d], rumen atony (reduced rumen contractions) Snoring Premature parturition, uterine disorder[e] Polyuria (increased urination)

[a] Reversible.
[b] Depending on the ambient temperature.
[c] Atony (reduced muscle tone).
[d] For 24 hours, after high doses of xylazine.
[e] Reduced implantation of the ovum.

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Abnormal behaviour[a] Hypothermia (low body temperature)[b] Hypotension (low blood pressure)[c]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bradycardia (severe-slow heart rate), arrhythmia (irregular heartbeat)[d] Hyperthermia (high body temperature)[b] Respiratory depression, respiratory arrest Increased sweating[e] Muscle tremor, ataxia (incoordination) Colic (mild)[f], digestive tract hypomotility (temporary)[f]
Undetermined frequency (cannot be estimated from the available data):	Penile prolapse[d] Hypertension (high blood pressure)[c] Involuntary movement[g] Decreased respiratory rate Frequent urination

[a] Violent reactions have been reported following the administration of xylazine.
[b] Depending on the ambient temperature.

[c] Transient rise in blood pressure, followed by a fall in blood pressure usually occurs.
[d] Reversible.
[e] When the effects of the sedation are wearing off.
[f] As a preventive measure the horse should receive no feed after sedation until the effect has faded completely.
[g] In response to sharp auditory or physical stimuli.

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 its local representative 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.
To ensure a correct dosage body weight should be determined as accurately as possible.

Cattle:

Dosage:

Dosage for cattle			
Dosage level*	xylazine (mg/kg)	Nerfasin vet. 100 mg/ml (ml/100 kg)	Nerfasin vet. 100 mg/ml (ml/500 kg)
I	0.05	0.05	0.25
II	0.1	0.1	0.5
III	0.2	0.2	1
IV	0.3	0.3	1.5

*Dose I: Sedation, with a slight decrease of muscle tone. The ability to stand is maintained.
Dose II: Sedation, marked decrease of muscle tone and some analgesia. The animal usually remains standing, but may lie down.
Dose III: Deep sedation, further decrease of muscle tone and a degree of analgesia. The animal lies down.
Dose IV: Very deep sedation, a profound decrease in muscle tone and a degree of analgesia. The animal lies down.

Horses
Dosage: single dose of 0.6 – 1 mg xylazine per kg body weight.

(0.6 – 1 ml of the veterinary medicinal product per 100 kg body weight).

9. Advice on correct administration

The intravenous injection to horses should be given slowly.
The stopper should not be punctured more than 20 times.
The number of punctures should be recorded on the outer packaging.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.

Do not refrigerate or freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the vial and the carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.
When the container is broached for the first time, the date on which any product remaining in the container should be discarded should be determined. This date should be written in the space provided on the outer package.

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.

Any unused product must be disposed of in accordance with the Misuse of Drugs Regulations 2001.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 19994/4018

Pack sizes:
Cardboard box with 1 vial containing 10 ml, 25 ml or 50 ml.
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:
Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse reactions:
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

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

17. Other information

POM-V

Approved 30 September 2026
Gavin Hall