1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dorvexa Vet 20 mg/ml, solution for injection for cattle, horses, dogs, cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml solution for injection contains:

Active substances:

Xylazine 20.00 mg
(equivalent to 23.32 mg xylazine hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	1.5 mg
Sodium chloride	
Sodium hydrogen carbonate (for pH adjustment)	
Water for injections	

Clear almost colourless solution, free of visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, dogs and cats.

3.2 Indications for use for each target species

Cattle:
For sedation, muscle relaxation, and analgesia during minor procedures. In combination with other anaesthetics.

Horses:
For sedation and muscle relaxation. In combination with other analgesics and anaesthetics.

Dogs, cats:
For sedation. In combination with other analgesics, anaesthetics and muscle relaxants.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of respiratory dysfunction or cardiac disorders (especially in cases of ventricular arrhythmia).
Do not use in cases of impaired hepatic or renal function.
Do not use in cases of predetermined history of seizures.
Do not use in cases of hypotension or shock.
Do not administer simultaneously with sympathomimetic amines (e.g. epinephrine).
Do not use in cases of diabetes mellitus.

Do not use in animals with confirmed gastrointestinal obstruction as xylazine is a muscle relaxant which may exacerbate the effects of the obstruction and increase the risk of vomiting.
Do not use in calves younger than 1 week of age, foals younger than 2 weeks of age or in puppies and kittens younger than 6 weeks of age.
Especially in cattle, xylazine should not be used in the last trimester of gestation, due to the risk of uterine contractions and premature birth.
Please refer to Section 3.7 Use during pregnancy, lactation or lay.

3.4 Special warnings

After administration, the animal should be allowed to rest in peace and quiet until full effect has been achieved.
For painful procedures, xylazine should always be used in combination with local or general anaesthesia.
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 veterinary medicinal 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.
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.

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.

Dogs, cats
Xylazine inhibits normal intestinal motility. Xylazine sedation may complicate the interpretation of upper gastrointestinal radiographs, due to gaseous distension of the stomach.
Brachycephalic dogs with airway disease or malfunction may develop life-threatening dyspnoea.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Cattle, horses, dogs, cats:
Animals that have been sedated with xylazine should be handled with care, as they may respond to external stimuli and can suddenly make targeted defensive movements.
Animals suffering from respiratory disease and/or breathing difficulty may develop life-threatening dyspnoea.
Xylazine may increase urine production and should therefore be used with caution in cases of urinary tract obstruction.
Older and exhausted animals are more sensitive to xylazine, whilst nervous or highly excitable animals may require a relatively high dose.

Xylazine should be used cautiously in dehydrated animals.
In diseases associated with sepsis and severe anaemia, the therapeutic index is reduced.
If premedication with other veterinary medicinal products (e.g., sedative/analgesic premedication) is administered before administering the veterinary medicinal product, the dose of the veterinary medicinal product should be reduced.
In horses, intra-arterial administration should be avoided.
Following administration of the veterinary medicinal product, animals should be monitored until they have fully recovered and should be kept separate from other animals to avoid bullying.
Sedation may impair thermoregulation. Following administration of the veterinary medicinal product, it may be necessary to cool animals when the ambient temperature is above 25 °C and to keep animals warm at low temperatures.
In cases of prolonged post-anaesthetic sedation, ensure animals are protected from hypothermia and direct sunlight.
Do not exceed the recommended dosage.

Cattle:
To avoid aspiration of food and saliva, lower the animal's head and neck.
Tympany, which sometimes occurs in recumbent ruminants, should be relieved by raising them to the sternal position or similar.
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, life-threatening adverse reactions may occur after intramuscular doses of more than 0.5 mg/kg body weight (respiratory and circulatory failure). Therefore, very precise dosing is required.

Horses:
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.

Cats and dogs:
Ketamine should only be administered after successful sedation with the veterinary medicinal product.
Emesis is generally seen within 3 - 5 minutes after xylazine administration in cats and dogs.
Cats and dogs should be fasted for 12 hours before injection of the veterinary medicinal product due to the risk of vomiting. They may have free access to drinking water.
Pre-medication with atropine in cats and dogs may reduce salivation and bradycardia effects.

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

This veterinary medicinal product may cause hypersensitivity reactions (allergies). People with known hypersensitivity to xylazine hydrochloride or parabens should avoid contact with the veterinary medicinal product.
This veterinary medicinal 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, 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 amount of water.
In case of accidental contact of the veterinary medicinal product with eyes, rinse with large amounts of fresh water. If symptoms occur, seek medical advice.
Remove contaminated clothes that are in direct contact with skin.
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.

Advice to doctors:
Xylazine hydrochloride is an alpha2-adrenoceptor agonist. Symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported.
Respiratory and hemodynamic symptoms should be treated symptomatically.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Excitation[1] Arrhythmia, Bradycardia, Hypotension[2] Ruminal tympany, Decreased ruminal activity, Hypersalivation, Regurgitation Hyperglycaemia Tongue paralysis Polyuria Penile prolapse[3], Uterine contraction Respiratory arrest, Respiratory depression Skin irritation[3] Decreased body temperature[4], Elevated temperature[4]

[1] paradoxical
[2] after initial increase in blood pressure
[3] reversible
[4] inhibition of thermoregulation with a decrease in body temperature; after initial increase of body temperature

Horses:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Excitation[1] Arrhythmia, Bradycardia, Hypotension[2] Colic[3], Digestive tract hypomotility[3] Hyperglycaemia Polyuria Penile prolapse[4], Uterine contraction Respiratory arrest, Respiratory depression Skin irritation[4] Decreased body temperature[5]

[1] paradoxical
[2] after initial increase in blood pressure
[3] mild colic may occur after the use of substances with α2-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.
[4] reversible
[5] inhibition of thermoregulation with a decrease in body temperature

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Excitation[1] Arrhythmia, Bradycardia, Hypotension[2] Vomiting Hyperglycaemia Polyuria Respiratory arrest, Respiratory depression Skin irritation[3] Decreased body temperature

[1] paradoxical
[2] after initial increase in blood pressure
[3] reversible

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Excitation[1] Arrhythmia, Bradycardia, Hypotension[2] Vomiting Hyperglycaemia Polyuria Respiratory arrest, Respiratory depression Skin irritation[3] Decreased body temperature

[1] paradoxical
[2] after initial increase in blood pressure
[3]reversible

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

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Although laboratory studies in rats have not shown any evidence of teratogenic or foetotoxic effects, use only according to the benefit-risk assessment by the responsible veterinarian during the first two-thirds of pregnancy.
Do not use in the last third of pregnancy (particularly in cattle and cats), because xylazine causes uterine contractions and it may induce premature parturition.

Fertility:
Do not use in cattle receiving ovum transplants or in cattle at the time of implantation of the ovum 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

The veterinary medicinal product should not be used concomitantly with epinephrine, as the combination can cause ventricular arrhythmias.
Concomitant use of the veterinary medicinal product with other central nervous system depressants, such as barbiturates, narcotics and analgesics, may result in additive CNS depression. Therefore, a reduction in the dosage of these substances may be necessary.
Xylazine should be used cautiously in combination with neuroleptics or tranquillizers.
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/sulfonamide-containing products should not be undertaken when horses have been sedated with xylazine.
Xylazine can be antagonised by administration of α2-antagonists.

3.9 Administration routes and dosage

Cattle: intravenous or intramuscular use
Horse: intravenous use
Dog: intravenous or intramuscular use
Cat: intramuscular or subcutaneous use

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.
The intravenous injection should be administered slowly, especially in horses.

Cattle. Intravenous or intramuscular use

Intravenous use
When administering the veterinary medicinal product intravenously, the recommended dose is equivalent to 1/3 – 1/2 of the dose recommended for intramuscular administration, depending on the individual animal status.
Intravenous administration results in a more rapid onset of effect and usually a reduced duration of effect when compared with intramuscular administration

Dose Level	Xylazine mg per kg body weight (BW)	Veterinary medicinal product ml per 100 kg BW	Veterinary medicinal product ml per 500 kg BW
1	0.016 - 0.024	0.08 - 0.12	0.4 - 0.6
2	0.034 - 0.05	0.18 - 0.25	0.85 - 1.25
3	0.066 - 0.10	0.33 - 0.5	1.65 - 2.5

Intramuscular use

Dose Level	Xylazine mg per kg BW	Veterinary medicinal product ml per 100 kg BW	Veterinary medicinal product ml per 500 kg BW
1	0.05	0.25	1.25

2	0.1	0.5	2.5
3	0.2	1.0	5.0
4	0.3	1.5	7.5

If necessary, the effect of the veterinary medicinal product can be enhanced or prolonged by a second administration. To enhance the effect, the second dose is given 20 minutes after the first administration. For prolongation, the second dose is given 30-40 minutes after the first administration. However, the total dose administered should not exceed 0.3 mg/kg bodyweight.

Dose 1 (0.05 mg xylazine per kg BW, i.e. 0.25 ml of the veterinary medicinal product per 100 kg BW):
Leads to sedation with a slight decrease of muscle tone. The cattle are still able to stand.

Dose 2 (0.1 mg xylazine per kg BW, i.e. 0.5 ml of the veterinary medicinal product per 100 kg BW):
Causes moderate sedation, moderate muscle relaxation and slight analgesia. If recumbency is undesirable for the procedure, recumbent animals may be stimulated to rise.

Dose 3 (0.2 mg xylazine per kg BW, i.e. 1 ml of the veterinary medicinal product per 100 kg BW):
Causes deep sedation, significant muscle relaxation and partial analgesia. Recumbency is expected (prior withholding of feed is recommended).

Dose 4 (0.3 mg xylazine per kg BW, i.e. 1.5 ml of the veterinary medicinal product per 100 kg BW):
Causes prolonged sedation, profound muscle relaxation and partial analgesia. Recumbency is expected. Should only be used in exceptional cases after fasting for several hours.

Horse. Intravenous use
0.6–1.0 mg xylazine per kg BW (corresponding to 3–5 ml of the veterinary medicinal product per 100 kg BW)

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

Possible combinations with other veterinary medicinal products:

a. For surgery on a standing animal:

Veterinary medicinal product with levomethadone hydrochloride and fenpipramide hydrochloride:

0.4–0.6 mg xylazine per kg BW intravenously (corresponding to 2–3 ml of the veterinary medicinal product per 100 kg BW) in combination with a veterinary medicinal product containing levomethadone hydrochloride and fenpipramide hydrochloride. The lower end of the authorised dose range of the levomethadone hydrochloride/fenpipramide hydrochloride veterinary medicinal product should be used.

b. As premedication for surgery on a recumbent animal, to allow recumbency, or for short-term anaesthesia:
Veterinary medicinal product in combination with ketamine:
1 mg xylazine per kg BW intravenously (corresponding to 5 ml of the veterinary medicinal product per 100 kg BW) and, after onset of deep sedation, 2 mg ketamine per kg BW intravenously.

Dog. Intravenous or intramuscular use
Intravenously: 1 mg xylazine per kg BW (corresponding to 0.5 ml of the veterinary medicinal product per 10 kg BW)

Intramuscularly: 1-3 mg xylazine per kg BW (corresponding to 0.5- 1.5 ml of the veterinary medicinal product per 10 kg BW)

Depth and duration of effects are dose dependent. Light to deep sedation and decrease in muscle tone as well as individually variable analgesia is obtained.

Possible combinations with other veterinary medicinal products:

Veterinary medicinal product with levomethadone hydrochloride and fenpipramide hydrochloride:

2 mg xylazine per kg BW intramuscularly (corresponding to 1 ml of the veterinary medicinal product per 10 kg BW) in combination with a veterinary medicinal product containing levomethadone hydrochloride and fenpipramide hydrochloride. The lower end of the authorised dose range of the levomethadone hydrochloride/fenpipramide hydrochloride veterinary medicinal product should be used.

If repeated doses of levomethadone hydrochloride and fenpipramide hydrochloride are required during longer procedures, the dose should be selected carefully and administered to effect. It may however be prudent to remain within the indicated dose range for each individual dose administered.

Veterinary medicinal product in combination with ketamine:

2 mg xylazine per kg BW intramuscularly (corresponding to 1 ml of the veterinary medicinal product per 10 kg BW) and 6-10 mg ketamine per kg BW intramuscularly

Administration of the veterinary medicinal product can cause vomiting in dogs. This effect can be reduced, if undesirable, by fasting the dog.

Cat, Intramuscular or subcutaneous use
Intramuscularly: 2 mg xylazine per kg BW (corresponding to 0.1 ml of the veterinary medicinal product per kg BW).
Subcutaneously: 2-4 mg per kg BW (corresponding to 0.1 - 0.2 ml of the veterinary medicinal product per kg BW)

Semi-domesticated as well as nervous and agitated animals, generally require a slightly higher dose.
Older or diseased animals, as well as animals subjected to intense physical activity prior to treatment, may show increased response to the veterinary medicinal product.
Depth and duration of the effect are dose dependent. Light to deep sedation and decrease in muscle tone as well as individually variable analgesia is obtained.

Possible combinations with other veterinary medicinal products:

Veterinary medicinal product in combination with ketamine:
Up to 2 mg xylazine per kg BW intramuscularly (corresponding to up to 0.1 ml of the veterinary medicinal product per kg BW) and 5-15 mg ketamine per kg BW intramuscularly.

Administration of the veterinary medicinal product can cause vomiting in cats. This effect can be reduced, if undesirable, by fasting the cat.

The stopper may be safely punctured up to 30 times using a 21G needle.
The stopper may be safely punctured up to 15 times using a 18G needle.
In case of excess broaching of the stopper, use a draw-off needle.

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

Cattle, horses, dogs, cats:
In the event of accidental overdose of the veterinary medicinal product, cardiac arrhythmias, hypotension, severe CNS and respiratory depression, and seizures may occur.

Artificial ventilation and centrally acting analeptics should be used.

Dogs, cats:
If required, xylazine can be antagonised by the administration of α2-adrenergic antagonists such as atipamezole.

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

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal periods

Cattle, horses:
Meat and offal: 1 day.
Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QNO5CM92

4.2 Pharmacodynamics

Xylazine is a thiazine derivative with sedative, hypnotic, local anaesthetic, and hypotensive effects. Depending on the animal species, it also exhibits analgesic and muscle relaxant properties. It is an α2-adrenergic receptor agonist 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 α2-adrenergic receptor. Some of the observed adverse effects appear to be based on the same mechanism of action.

4.3 Pharmacokinetics

Xylazine is rapidly absorbed and distributed throughout the body. Regardless of the animal species, the maximum plasma concentration is reached within 12–14 minutes after intramuscular injection. Bioavailability after intramuscular administration, however, depends on the species. Xylazine is extensively and rapidly metabolized into various metabolites. After intramuscular and intravenous administration, the half-life for elimination is 23–60 minutes. The half-life for complete elimination, regardless of the route of administration or dosage, is 2–3 hours. In a residue study in cattle with radiolabelled active ingredient, 85% of the administered radioactivity was excreted in the urine 24 hours after intravenous 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: 3 years
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

Do not refrigerate or freeze.

5.4 Nature and composition of immediate packaging

Clear glass vials type II closed with chlorobutyl rubber stopper type I and aluminum cap in a cardboard box

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

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

Forte Healthcare Licencing Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10806/010/001

8. DATE OF FIRST AUTHORISATION

01/10/2026

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

01/10/2026

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).