1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazine 20 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Xylazine base 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	1.8
Propyl parahydroxybenzoate	0.2
Hydrochloric acid, concentrated	
Sodium Citrate	
Citric acid monohydrate	
Sodium chloride	
Water for injection	

Clear, colourless aqueous solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, dogs and cats.

3.2 Indications for use for each target species

This veterinary medicinal product is a sedative with analgesic and muscle relaxant properties for use in cattle, horses, dogs and cats in cases where sedation is required including:

1. Handling fractious animals e.g. for transportation.
2. Medical examinations e.g. X-ray examinations, removal of bandages, examination of the penis and oral cavity.
3. Premedication for minor superficial operations, and local or regional anaesthesia.
4. Elimination of defaecation when examining and treating the vagina, uterus and hindquarters.

3.3 Contraindications

Do not administer by the intra-carotid route.
Do not use in:
- diabetes mellitus.
- gastrointestinal obstruction.
- heart or lung disease.
- the first trimester or the last month of pregnancy.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Cattle:
Tympany should be avoided in recumbent cattle by maintaining the animal in sternal recumbency. Provision should also be made for facilitating dependant drainage from the mouth to avoid inhalation asphyxia.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The use of xylazine should be carefully considered in cases of cardiac aberrations, arterial hypotension/shock and renal or hepatic impairment.

Careful consideration should also be given before administering to animals exposed to stress conditions such as extreme heat, cold, high altitude or fatigue.

In larger animals xylazine is not an ideal sedative for Caesarean section because of its oxytocic effect which impedes uterine suturing.
Older, sick or physically stressed animals may require a lower dose. Protect from hypothermia and intense heat during recovery. Segregate sedated animals to avoid bullying.

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

Xylazine is an alpha2-adrenergic agonist.
Precaution should be taken to avoid accidental injection/self-injection.

1. In case of accidental ingestion 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.
2. Avoid skin, eye or mucosal contact.
3. Immediately after exposure, wash the exposed skin with large amounts of fresh water.
4. Remove contaminated clothes that are in direct contact with skin.
5. In case of accidental contact of the veterinary medicinal product with eyes, rinse with large amounts of fresh water. If symptoms occur, seek the advice of a doctor.
6. 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.
7. Advice to Doctors: Xylazine is an alpha2-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	Hypersalivation, gastric bloat, Hyperglycaemia, polyuria Bradycardia, arrhythmia, respiratory depression, impaired thermo-regulation

Horses:

Undetermined frequency (1 to 10 animals / 10 000 animals treated):	Hypertension[1], Hypotension[1]

[1] Transient rise followed by a fall. Following intravenous administration.

Dogs and cats:

Common (1 to 10 animals / 100 animals treated):	Vomiting
Undetermined frequency:	Injection site pain[1,2]

[1] Following intramuscular administration.
[2] Massage injection site well following administration.

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 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 and lactation:
This veterinary medicinal product should not be administered during the last month of pregnancy because of the risk of inducing premature parturition.

As the safety of xylazine use during organogenesis has not been fully demonstrated by current methods it should not be used during the first trimester of pregnancy.
Not permitted for use in lactating cattle producing milk for human consumption.

3.8 Interaction with other medicinal products and other forms of interaction

Analeptics will reduce the depth or shorten the period of sedation.
See also section 3.9.

3.9 Administration routes and dosage

Cattle, dogs and cats: Intramuscular use. Horses: Intravenous use.

Cattle:
This veterinary medicinal product is given by intramuscular injection. The dose rate is 0.05 - 0.3 mg/kg (0.25 ml - 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	mg/kg	mg/50 kg	ml/50 kg
1	0.05	2.5	0.12
2	0.1	5.0	0.25
3	0.2	10.0	0.5
4	0.3	15.0	0.75

Dose 1: Sedation with slight decrease in muscle tone.
Dose 2: Sedation marked decrease in muscle tone and some analgesia. The animal usually remains standing.
Dose 3: Deep sedation, further decrease in muscle tone and a useful degree of analgesia. The animals lies down.
Dose 4: Very deep sedation, a profound decrease in muscle tone and a useful degree of analgesia. The animal lies down.

Animals should not be disturbed until the veterinary medicinal product has taken its full effect. Onset of the effect is usually seen within 15 minutes and effects persist for approximately 45-60 minutes depending on the dosage rate used. Induction and recovery are smooth. Local anaesthetics should be used in combination with the veterinary medicinal product where major surgical treatment is carried out.

Horses:
This veterinary medicinal product is given by slow intravenous injection. Dosage depends upon the degree of sedation required and the response of the animal and is 0.6 - 1 mg/kg (3 - 5 ml/100 kg) bodyweight. The horse does not usually become recumbent with the veterinary medicinal product and light to deep sedation with variable degree of analgesia is obtained. Animals should not be disturbed until the veterinary medicinal product has taken its full effect. Effects are usually seen within 5 minutes and persist for approximately 20 minutes.
This veterinary medicinal product may be employed in the horse as a premedication to barbiturate anaesthesia or in combination with regional or local anaesthesia. When used as a pre-anaesthetic medication the dose rate of barbiturate should be reduced to a quarter to half of normal.

Nervous or excitable horses may require higher doses. Older horses and those having undergone severe physical exertion before treatment should receive the lowest dose rate.

Dogs:
This veterinary medicinal product is administered intramuscularly at dose rates of 1 - 3 mg/kg (0.05 - 0.15 ml/kg), bodyweight. For painful procedures it may be used in combination with a local anaesthetic. Premedication with atropine may be desirable in some cases. This veterinary medicinal product is synergistic with the barbiturates and reduces the dosage of the latter by approximately one half.

Cats:
This veterinary medicinal product is administered intramuscularly at a dose rate of 3 mg/kg (0.15 ml/kg bodyweight). Premedication with atropine may occasionally be desirable.

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

Alpha-2 blockers such as atipamezole are effective in reversing the sedation and other physiological effects of xylazine. Atropine may be used to reverse bradycardia and hypotension. Doxapram may be used to reverse respiratory depression.

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

Horses:
Meat and offal: 5 days.

Cattle:
Meat and offal: 5 days.
Milk: not permitted for use in lactating cattle producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QN05CM92

4.2 Pharmacodynamics

This veterinary medicinal product is an injectable solution containing Xylazine Base 20 mg/ml. Xylazine is an alpha$_2$-adrenergic drug with sedative, analgesic and muscle relaxing properties which acts via the CNS. Xylazine is thought to act by activation of the central presynaptic alpha$_2$-receptors. Activation of these central alpha$_2$-receptors seems to regulate central dopamine and norepinephrine storage or release. Xylazine's analgesic and sedative actions are related to its central nervous system depression, while the muscle relaxant effects are due to the inhibition of the intraneural transmission of impulses in the central nervous system.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Mixing of xylazine with other agents in the same syringe is not advised.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Once broached use within 6 months.

5.3 Special precautions for storage

Store below 25 °C.

5.4 Nature and composition of immediate packaging

Cardboard box with one 30 ml amber injection vials, Type I Ph. Eur. glass containing 25 ml of clear, colourless sterile solution.Elastomeric closures 20 mm.
Aluminium seals with removable centres.

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.

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

Chanelle Pharmaceuticals Manufacturing Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/030/001

8. DATE OF FIRST AUTHORISATION

01/10/1990

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

12/03/2026

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).