1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazine 100 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Xylazine base 100 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 mg
Propyl Parahydroxybenzoate	0.2 mg
Hydrochloric acid, concentrated	/
Sodium citrate	/
Citric acid monohydrate	/
Water for injection	/

Clear, colourless solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

The veterinary medicinal product is a sedative with analgesic and muscle relaxant properties for use in horses only, 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 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

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Xylazine is not an ideal sedative for caesarean section because of its oxytoxic effect which impedes uterine suturing.
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.
Protect from hypothermia and intense heat during recovery.

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

Xylazine is an alpha2-adrenergic agonist.
The usual precautions for handling animals should be observed even when a high dose of this veterinary medicinal product has been given.
Precaution should be taken to avoid accidental injection/self-injection.

1. In case of accidental oral 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 the 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

Horses:

Undetermined frequency	Hypertension[1], Hypotension[1] Bradycardia, arrhythmia Polyuria.

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

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:

The 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.

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

Intramuscular or Intravenous use.

This veterinary medicinal product is given by intramuscular or intravenous administration. Intravenous injection should be slow taking from one to two minutes to administer. Dosage depends on the degree of sedation required and the response of the animal. This veterinary medicinal product is administered by intravenous injection at a dose rate of 0.5 - 1 ml/100 kg bodyweight (0.5 - 1 mg/kg) or intramuscularly at a dose rate of 1 - 2 ml/100 kg bodyweight (1 - 2 mg/kg). Animals do not usually become recumbent with this veterinary medicinal product and light to deep sedation with variable degree of analgesia is obtained. Effects are usually seen within 10 to 15 minutes after intramuscular administration and within 5 minutes following intravenous administration. A sleep-like state the depth of which is dose dependent is usually maintained for 1 - 2 hours, while analgesia lasts from 15 - 30 minutes. This veterinary medicinal product may be employed as a pre-medication to barbiturate anaesthesia or in combination with regional or local anaesthesia. When used as a pre-anaesthesia 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.

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.

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

Meat and offal: 5 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QN05CM92

4.2 Pharmacodynamics

This veterinary medicinal product is an injectable solution containing Xylazine Base 100 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.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

Store below 25 °C

5.4 Nature and composition of immediate packaging

Cardboard box with one 55 ml amber injection vials, Type I Ph. Eur. glass containing 50 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)

VPA10987/031/001

8. DATE OF FIRST AUTHORISATION

01/10/1990

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

01/04/2026

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).