SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazine 10% Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Xylazine 100 mg/ml

Excipient(s):
Methyl Parahydroxybenzoate 1.8 mg/ml
Propyl Parahydroxybenzoate 0.2 mg/ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use,specifying the target species

Xylazine is a sedative with analgesic and muscle relaxant properties. The product is 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.

4.3 Contraindications

Do not administer by the intra-carotid route.
Careful consideration should be given before administering to animals exposed to stress conditions such as extreme heat, cold, high altitude or fatigue.

4.4 Special warnings for each target species

None known

4.5 Special precautions for use

i. Special precautions for use in animals

Should be used with caution when pulmonary disease is suspected.
Do not exceed the recommended dosage

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

Horses sedated with xylazine usually remain standing and may still kick with accuracy.
Precaution should be taken to avoid accidental injection / self-injection.

1. In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet to the doctor 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 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 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, brachycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.

4.6 Adverse reactions (frequency and seriousness)

Side effects of bradycardia, cardiac arrhythmia and polyuria may occur.
Following intravenous administration a transient rise followed by a fall in blood pressure usually occurs.

4.7 Use during pregnancy, lactation or lay

Xylazine should not be administered during the later stages 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 be used with caution during the first month of pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The product is given by slow intravenous injection. Dosage depends on the degree of sedation required and the response of the animal, and is 0.5 – 1 ml/100 kg (0.5 - 1 mg/ kg bodyweight). 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.

Animals do not usually become recumbent after administration and light to deep sedation with variable degree of analgesia is obtained. Effects are usually seen within 5 minutes and persist for approximately 20 minutes. The product may be employed as a premedication to barbiturate anaesthesia or in combination with regional or local anaesthesia.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Sedation is dose dependent and the occurrence of side effects will increase and worsen at higher dosage than recommended.

4.11 Withdrawal period(s)

Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

5. PHARMACOLOGICAL PROPERTIES

Sedative, analgesic and muscle relaxing properties
ATCvet code: QN05CM92

5.1 Pharmacodynamic properties

Xylazine is an α_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 α_2-receptors. Activation of these central α_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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate

Conc. Hydrochloric Acid
Sodium Citrate
Citric Acid Monohydrate
Water for Injection

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening of the immediate packaging: 28 days.

6.4. Special precautions for storage

Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

6.5 Nature and composition of immediate packaging

50 ml Amber injection vials, Type I Ph. Eur. glass. Elastomeric closures 20 mm. Aluminium seals with removable centres.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
H62 FH90
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 08749/5180

9. DATE OF FIRST AUTHORISATION

03 September 1991

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

September 2025

Gavin Hall
Approved: 11 November 2025