

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazine 2% Solution for Injection

Xylazine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of Chanazine 2% contains 20 mg xylazine

Preservatives:

Methyl parahydroxybenzoate 1.8 mg/ml

Propyl parahydroxybenzoate 0.2 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

25 ml

5. TARGET SPECIES

Horses, Cattle, Dogs and Cats

6. INDICATION(S)

A sedative with analgesic and muscle relaxant properties for use in cattle, horses, dogs and cats in cases where sedation is required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See package leaflet for details

8. WITHDRAWAL PERIOD

Cattle (meat): 14 days

Not for use in animals from which milk is produced for human consumption.

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

9. SPECIAL WARNING(S), IF NECESSARY

Operator Warnings:

Alpha 2-adrenoreceptor agonists can cause severe adverse reactions. You must read the warnings on the package leaflet before using the product.

Contraindications:

Do not administer by the intra-carotid route. Do not administer during the later stage of pregnancy because of the risk of inducing premature parturition.

See package leaflet for further contraindications and general precautions.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product or containers in accordance with guidance from your local waste regulatory authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

POM-V

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9HZ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11990/4005

17. MANUFACTURER’S BATCH NUMBER

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Chanelle Animal Health Ltd, 7 Rodney Street, Liverpool, L1 9HZ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazine 2% Solution for Injection

Xylazine

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Chanazine 2% is a clear, colourless aqueous solution for injection.

Each ml of Chanazine 2% contains 20 mg xylazine

Preservatives:

Methyl parahydroxybenzoate 1.8 mg/ml

Propyl parahydroxybenzoate 0.2 mg/ml

4. INDICATION(S)

Chanazine 2% 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 defecation when examining and treating the vagina, uterus and hindquarters.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Following the use of Chanazine 2% in cattle profuse salivation, bloat and polyuria may occur.

Tympany should be avoided in recumbent cattle by maintaining the animal in sternal recumbency.

Provision should also be made for facilitating dependent drainage from the mouth to avoid inhalation asphyxia.

Side effects such as bradycardia, cardiac arrhythmia and polyuria may occur in the horse.

Following intravenous administration to horses a transient rise followed by a fall in blood pressure usually occurs.

Vomiting is commonly observed in dogs and cats following use of the product.

7. TARGET SPECIES

Horses, Cattle, Dogs and Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cattle:

Chanazine 2% is given by intramuscular injection.

The dose rate is 0.05-0.3 mg/kg (0.25-1.5 ml /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 rate 4).

<i>Dose</i>	<i>mg/kg</i>	<i>mg/50 kg</i>	<i>ml/50 kg</i>
1	0.05	2.5	0.12
2	0.10	5.0	0.25
3	0.20	10	0.50
4	0.30	15	0.75

Horses:

Chanazine 2% 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. 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. The horse does not usually become recumbent with Chanazine 2% 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. Chanazine 2% may be employed in the horse as a premedication to barbiturate anaesthesia or in combination with regional or local anaesthesia.

Dogs:

Chanazine 2% is administered intramuscularly at dose rates of 1 - 3 mg/kg (0.05 - 0.15 ml/kg bodyweight). It may be used in combination with a local anaesthetic. Premedication with atropine may be desirable in some cases. Chanazine 2% is synergistic with the barbiturates and reduces the dosage of the latter by approximately one half.

Cats:

Chanazine 2% is administered intramuscularly at a dose rate of 3 mg/kg (0.15 ml/kg bodyweight). Premedication with atropine may occasionally be desirable.

9. ADVICE ON CORRECT ADMINISTRATION

Do not repeat the dose in the event of an unsatisfactory response. Repeat the following day with a recalculated dosage.

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 14 days from the last treatment.

Not for use in animals from which milk is produced for human consumption.

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.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. For the ease of calculation of dates, the date of broaching of the product must be written in the box provided on the bottle. Keep container in outer carton.

12. SPECIAL WARNING(S)

Chanazine 2% 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.

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 the 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.

For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product or containers in accordance with guidance from your local waste regulatory authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription.

Vm 11990/4005

Package quantities: Vials of 25 ml

Keep out of the reach of children.

Approved: 04/01/2018

