PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazine 10% Solution for Injection, Xylazine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of Chanazine 10% contains 100 mg Xylazine Base

Preservatives:

Methyl Parahydroxybenzoate – 1.8 mg/ml

Propyl Parahydroxybenzoate – 0.2 mg/ml

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

A sedative with analgesic and muscle relaxant properties for use in horses only in cases where sedation is required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See package leaflet for details

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer by the intra-carotid route.

Do not administer during the later stages of pregnancy because of the risk of inducing premature parturition.

See package leaflet for further contra-indications and general precautions.

Operator Warnings:

Alpha 2-adrenoreceptor agonists can cause severe adverse reactions.

You must read the warnings on the package leaflet before using this product.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Keep the container in the outer carton.

Do not store above 25°C

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 regulation authority.

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

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 11990/4006

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanzine 10% Solution for Injection, Xylazine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml of Chanazine 10% contains 100 mg Xylazine Base

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

Preservatives:

Methyl Parahydroxybenzoate……..1.8 mg/ml

Propyl Parahydroxbenzoate……0.2 mg/ml

4. ROUTE(S) OF ADMINISTRATION

Solution for Injection

5. WITHDRAWAL PERIOD

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.

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

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 10% Solution for Injection

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

Chanazine 10% is a clear colourless aqueous solution for injection. Each ml contains 100 mg Xylazine. Contains Methyl Parahydroxybenzoate 1.8 mg/ml and Propyl Parahydroxybenzoate 0.2 mg/ml as antimicrobial preservatives.

4. INDICATION(S)

Chanazine 10% is a desative with analgesic and muscle relaxant properties for use in horses only. Chanazine 10% can be used in many cases where sedation is required, including:

1. Handling fractious animals e.g. for transportation.
2. Medical examinations e.g. X-ray examination, removal of bandages, examination of the teats, 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

5. CONTRAINDICATIONS

Do not exceed the recommended dosage.
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.
Side effects such as bradycardia, cardiac arrhythmia and polyuria may occur.
Following intravenous administration a transient ride followed by a fall in blood pressure usually occurs.
Chanazine 10% 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.

6. ADVERSE REACTIONS

7. TARGET SPECIES

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

Chanazine 10% is given by slow intravenous injection. Dosage depends upon the degree of sedation required and the response of the animals, 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 with Chanazine 10% and light to deep sedation with variable degree of analgesia is persist for approximately 20 minutes. Chanazine 10% may be employed in the horse as a premedication to barbiturate anaesthesia or in combination with regional or local anaesthesia.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

No 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.

Keep container in outer carton.

12. SPECIAL WARNING(S)

Operator Warnings:
Horses sedated with xylazine usually remain standing and may still kick with accuracy. Precautions 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, bradycardia, hypotension, a dry mouth and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.

General Precautions:
Keep out of the reach of children
For Animal Treatment only

Pharmaceutical Warnings:
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 label.

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 regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription

Vm 11990/4006

Package Quantities: Vials of 50ml

Approved: 08/05/2018