Summary of Product Characteristics

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazine 2% Solution for Injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active Substance:
Xylazine Base 20 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle, horses, dogs and cats.

4.2 Indications for use, specifying the target species

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 defaecation when examining and treating the vagina, uterus and hindquarters.

4.3 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
• cases of known hypersensitivity to the active ingredient

4.4 Special warnings for each target species

Cattle:
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.
Not permitted for use in lactating cattle producing milk for human consumption.

4.5 Special precautions for use
**Special precautions for use in animals**

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**

Chanazine is an alpha_2_ adrenergic agonist.

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-adrenoceptor 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.

**4.6 Adverse reactions (frequency and seriousness)**

Following use of Chanazine 2% in cattle, profuse salivation, bloat and polyuria may occur. Bradycardia, cardiac arrhythmia, respiratory depression, impaired thermo-regulation, hyperglycemia and polyuria may occur. 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 preparation. Pain may occur at the injection site following intramuscular administration in cats and dogs, massage injection site well following administration.

**4.7 Use during pregnancy, lactation or lay**

Chanazine 2% 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.

**4.8 Interaction with other medicinal products and other forms of interaction**
Analeptics will reduce the depth, or shorten the period of sedation. See also clause 4.9.

4.9 Amounts to be administered and administration route

**Cattle:**
Chanazine 2% 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.

<table>
<thead>
<tr>
<th>Dose</th>
<th>mg/kg</th>
<th>mg/50 kg</th>
<th>ml/50 kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.05</td>
<td>2.5</td>
<td>0.12</td>
</tr>
<tr>
<td>2</td>
<td>0.1</td>
<td>5.0</td>
<td>0.25</td>
</tr>
<tr>
<td>3</td>
<td>0.2</td>
<td>10.0</td>
<td>0.5</td>
</tr>
<tr>
<td>4</td>
<td>0.3</td>
<td>15.0</td>
<td>0.75</td>
</tr>
</tbody>
</table>

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 Chanazine has taken its full effect. Onset of 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 Chanazine where major surgical treatment is carried out.

**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. The horse does not usually become recumbent with Chanazine 2% and light to deep sedation with variable degree of analgesia is obtained. Animals should not be disturbed until Chanazine has taken its full effect. 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. 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:**
Chanazine 2% 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. 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.
4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal Period(s):

**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.

5. **PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Nervous system, psycholeptics, hypnotics and sedatives; xylazine.
ATC vet code: QN05CM92

Chanazine 2% 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.

6. **PHARMACEUTICAL PARTICULARS**

6.1 Incompatibilities:

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

6.2 Shelf-life:

5 years
Following withdrawal of the first dose, use the product within 6 months.

6.3 Special precautions for storage:

Store below 25°C.

6.4 Nature and composition of immediate packaging:

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

6.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials:
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,
Ireland.