Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanazine 10% Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Xylazine Base	100	mg

Excipients

Methyl Parahydroxybenzoate	1.8	mg
Propyl Parahydroxybenzoate	0.2	mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses.

4.2 Indications for use, specifying the target species

Chanazine 10% 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.

4.3 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 known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
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
Chanazine is an alpha2-adrenergic agonist.
The usual precautions for handling animals should be observed even when a high dose of Chanazine has been given.
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, 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)

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

Chanazine 10% 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.

4.8 Interaction with other medicinal products and other forms of interactions

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

Chanazine 10% 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. Chanazine 10% 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 Chanazine 10% 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. Chanazine 10% 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.

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.

4.11 Withdrawal period(s)

Meat and offal: 5 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

Chanazine 10% 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Hydrochloric acid, concentrated
Sodium citrate
Citric acid monohydrate
Water for injection

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicnal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 6 months.

6.4 Special precautions for storage

Store below 25^{o}C.

6.5 Nature and composition of immediate packaging

50 ml of clear, colourless sterile solution contained in 55 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 products or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/031/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1990
Date of last renewal: 30 September 2010

10 DATE OF REVISION OF THE TEXT

September 2010