SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xylacare 2% w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Qualitative composition	Quantitative composition mg/ml
Xylazine	20.0

Excipients

Methyl parahydroxybenzoate	1.8
Propyl parahydroxybenzoate	0.2

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.

A clear, colourless solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses, dogs and cats.

4.2 Indications for use, specifying the target species

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. Pre-medication for minor superficial operations, and local or regional anaesthesia.
4. Elimination of defecation when examining and treating the vagina, uterus and hind-quarters.

4.3 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.

4.4 Special warnings for each target species

Cattle are about ten-times more sensitive to Xylazine than horses and higher doses will cause recumbency.

4.5 Special precautions for use

i. Special precautions for use in animals

Care should be exercised in administration to aged or debilitated animals.

ii. Special precautions for 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.
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.
Avoid skin, eye or mucosal contact.
Immediately after exposure, wash the exposed skin with large amounts of fresh water.
Remove contaminated clothes that are in direct contact with skin.
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.
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.

Advice to doctors: Xylazine is an alpha2-adrenoreceptor agonist. Symptoms after absorption may involve clinical effects including dose-dependant sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.

iii. Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

Following use in cattle, profuse salivation, bloat and polyuria may occur. 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.
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.

4.7 Use during pregnancy, lactation or lay

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 Amount(s) to be administered and administration route

Cattle:
The product 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).

Dose	mg/kg	mg/50 kg	ml/50 kg
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:
The product 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 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. Xylacare 2% may be employed in the horse as a premedication to barbiturate anaesthesia or in combination with regional or local anaesthesia.

Dogs:
The product 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. Xylacare 2% is synergistic with the barbiturates and reduces the dosage of the latter by approximately one half.

Cats:
The product 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.

4.11 Withdrawal period(s)

Cattle (Meat and Offal): 14 days

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.

Not to be used in animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Hypnotics and sedatives

ATC Vet Code:

QN05CM92

5.1 Pharmacodynamic properties

An injectable solution containing Xylazine Base 20 mg/ml. Xylazine is an α2-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 α2-receptors. Activation of these central α2-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.

5.2 Pharmacokinetic properties

Onset and duration of sedation is species-dependent varying from 5 to 15 minutes in horses to 15 to 30 minutes in dogs and cats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Hydrochloric Acid, Concentrated (for pH adjustment)
Sodium Citrate Dihydrate
Citric Acid Monohydrate
Sodium Chloride
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 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

25ml, Amber type 1 glass vial with a chlorobutyl rubber bung with an aluminium overseal.

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

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

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

8. MARKETING AUTHORISATION NUMBER

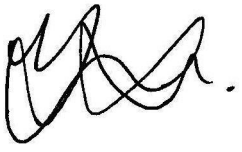
Vm 32742/4036

9. DATE OF FIRST AUTHORISATION

30 August 2000

10. DATE OF REVISION OF THE TEXT

August 2022



Approved: 11 August 2022