PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xylacare 2% w/v

Xylazine 20 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Preservatives: Methyl Parahydroxybenzoate 1.8mg/ml, Propyl Parahydroxybenzoate 0.2mg/ml.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

25ml

5. TARGET SPECIES

Cattle, horses, 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

Dosage and administration, contra-indications and general precautions: See package leaflet

8. WITHDRAWAL PERIOD

Cattle (meat) 14 days. Not to be used in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store below 25^{o}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

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

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

To be supplied only on veterinary prescription.

POM-V

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

Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4036

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xylacare 2% w/v

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Xylazine 20mg/ml Solution for Injection

Preservatives:

Methyl Parahydroxybenzoate 1.8mg/ml,
Propyl Parahydroxybenzoate 0.2mg/ml.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

25ml

5. TARGET SPECIES

Cattle, horses, 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 producing milk for human consumption. Not to be used in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Operator warnings: Alpha2-adrenoreceptor agonists can cause severe adverse reactions. You must read the warnings on the package leaflet before using this product.

Contra-indications: 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.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store below 25ºC. Discard unused material.

Keep vial in outer carton.

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

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

To be supplied only on veterinary prescription.

POM-V

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

Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4036

17. MANUFACTURER'S BATCH NUMBER

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

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

Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium

Manufactured in the EU

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xylacare 2% Solution for Injection

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

Presentation:

Xylacare 2% is a clear, colourless aqueous solution for injection. Each ml contain 20mg Xylazine base. Contains methyl hydroxybenzoate 1.8mg/ml and propyl hydroxybenzoate 0.2mg/ml as preservatives.

4. INDICATION(S)

Xylacare 2% is a sedative with analgesic and muscle relaxant properties for use in cattle, horses, dogs and cats 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.

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.

Xylacare 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.

6. ADVERSE REACTIONS

Following the use of Xylacare 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

Cattle, horses, dogs and cats

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

Cattle:

Xylacare 2% is given by intramuscular injection taking precautions against contamination

The dose rate is 0.05-0.3 mg/kg xylazine (0.25-1.5 ml xylacare 2% per 100 kgbodyweight), 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:

Xylacare 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 Xyalcare 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. Xylacare 2% may be employed in the horse as a premedication to barbiturate anaesthesia or in combination with regional or local anaesthesia.

Dogs:

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

Cats:

Xylacare 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

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Pharmaceutical precautions: Store below 25^{o}C. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Keep vial in outer carton. When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. The discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Protection of consumers:

Animals must not be slaughtered for human consumption during treatment. Cattle must be slaughtered for human consumption only after 14 days from the last treatment. Not for use in animals from which milk is produced. Not to be used in horses 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.

Operator warnings:

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.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

To be supplied only on veterinary prescription.

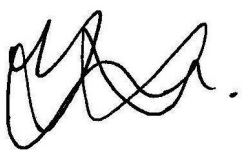
POM-V

Vm 32742/4036

Keep out of reach of children

For animal treatment only

Package quantities: Vials of 25ml.



Approved: 11 August 2022