PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON
XYLAPAN 20MG SOLUTION FOR INJECTION

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xylapan 20mg SOLUTION FOR INJECTION

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Xylazine (as hydrochloride)	20.0 mg
Methyl parahydroxybenzoate (E218)	0.65 mg
Propyl parahydroxybenzoate (E216)	0.35 mg as preservatives

Excipients: Sodium chloride, water

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

10ml.
50ml.

5. TARGET SPECIES

Cattles, Horses, Cats, Dogs

6. INDICATION(S)

Sedative
For sedation in cattles, horses, dogs and cats. For further information, see package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For i.v. injection only to horses and i.m injection to cattle, dogs and cats. Avoid the introduction to contamination during use. For dosage and administration, see package leaflet.

8. WITHDRAWAL PERIOD

Cattle: Meat and offal: One day
Milk: Zero hours

Horses: Meat and offal: One day

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications and warnings:
See package leaflet.
Operator warnings:
Avoid self-injection. Alpha 2-adrenoceptor agonists can cause severe adverse reactions. You must read the warnings on the package leaflet before using this product.
User information: Following the withdrawal of the first dose use the product within 12 days. Discard unused material. Avoid the introduction of contamination. Keep the carton in outer carton.

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

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

Dispose of any unused product and empty 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]*

For animal treatment only.
To be supplied only on veterinary prescription.
POM-V
UK authorised Veterinary medicinal product.

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/5051

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - LABEL
XYLAPAN 20MG SOLUTION FOR INJECTION

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xylapan 20mg SOLUTION FOR INJECTION

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Xylazine (as hydrochloride)	20.0 mg
Methyl parahydroxybenzoate (E218)	0.65 mg
Propyl parahydroxybenzoate (E216)	0.35 mg as preservatives

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

10ml.
50ml.

5. TARGET SPECIES

Cattles, horses, cats and dogs.

6. INDICATION(S)

Sedative.
For sedation in cattle, horses, dogs and cats. For further information, see package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For i.v. injection only to horses and i.m injection to cattle, dogs and cats. Avoid the introduction of contamination during use. For dosage and administration, see package leaflet.

8. WITHDRAWAL PERIOD

Cattle: Meat and offal: One day
Milk: Zero hours

Horses: Meat and offal: One day

9. SPECIAL WARNINGS, IF NECESSARY

Contra-indications and warnings:
See package leaflet.
Operator warnings:
Avoid self-injection. Alpha 2-adrenoceptor agonists can cause severe adverse reactions. You must read the warnings on the package leaflet before using this product.

10. EXPIRY DATE

Exp:
Discard unused material 12 days after opening.
Once opened use by: / / .

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Keep container in outer carton

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

Dispose of any unused product and empty 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

For animal treatment only.
To be supplied only on Veterinary prescription.

POM-V

UK authorised medicinal product.

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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16. MARKETING AUTHORISATION NUMBER

Vm 08007/5051

17. MANUFACTURER'S BATCH NUMBER

Batch:

PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xylapan 20mg SOLUTION FOR INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

A clear colourless aqueous solution for injection. Each ml of solution contains 20mg xylazine as xylazine hydrochloride. Also contains methyl parahydroxybenzoate (E218) 0.065% w/v, and propyl parahydroxybenzoate (E216) 0.035% w/v. Also contains: Sodium chloride, water.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses, cats and dogs.

4.2 Indications for use, specifying the target species

A sedative, with analgesics and muscle relaxant properties, for use in cattle, horses, dogs and cats. In cattle the degree of sedation can be predetermined according to the dose administered.

Indications for use in cattle, horses, dogs and cats:
All cases where sedation is required including:
1. General handling and transport of nervous or fractious animals.
2. Medical examinations and treatments e.g.x-rays, oral, genital and rectal examinations.
3. Premedication for minor surgical interventions and for anaesthesia in conjunction with other analgesics, narcotics and inhalant anaesthetics.

4.3 Contra-indications

Not for use in the latter stages of pregnancy except at parturition.
In the cat and dog, because off the emetic effect which is sometimes produced, Xylapan should not be used if there are mechanical complications of the alimentary tract such as obstruction of the oesophagus, gastric torsion or hernia.

4.4 Special warnings for each target species

Undesirable effects (frequency and seriousness)
Transient hyperglycaemia is a common finding after Xylazine administration.

Horses
Following intravenous injection there is a transient rise followed by a fall of blood pressure. The usual precautions required for handling should always be observed even when a high dose of xylazine is given.

Cattle
The swallowing reflex is reduced during the period when the action of the drug is at its peak.
In recumbent cattle tympany should be prevented by maintaining sternal recumbency.
For operations in lateral or dorsal recumbency it is advisable to lower the head and neck in order to avoid inhalation of saliva and ruminal fluids. When high doses are to be employed the animal should be fasted for some hours beforehand. After dose levels 3 & 4, cattle are likely to remain drowsy for several hours and should be kept in the shade.

Cats and dogs
If the stomach is full, the vomiting occurs before sedation is complete. This is an advantage if general anaesthesia is to follow. The emetic effect is reduced by fasting for 6-24 hours before administration of Xylapan.

4.5 Special precautions for use

As safety of xylazine use during organogenesis has not been proven by current methods, care should be taken during the first month of pregnancy.
Care should be taken with aged animals or those with compromised lung function or suspected pulmonary disease since xylazine will depress respiration. In the event of respiratory failure, manual compression of the thorax is usually sufficient to restore normal respiration.
Calm, old, sick animals react more distinctly to Xylapan.
Sedated animals should be kept under supervision until normal, and they should be segregated to avoid bullying by others.

User Warnings

Xylazine is an alpha adrenoceptor agonist, acting primarily on alpha-2 receptors.
Care should be taken to avoid accidental injection/self-injection. It is recommended that, once the required dose has been withdrawn from the vial, the needle should be kept guarded until the product is administered. Alternatively, it should be removed from the syringe and immediately inserted into the injection site, and the syringe should then be connected to it.
Wash splashes from the skin and eyes immediately.
In the event of accidental injection/self-injection, seek urgent medical advice and show this label and other product literature.
DO NOT DRIVE as sedation and changes in blood pressure may ocur.
Advice to doctors:
Xylazine is an alpha adrenoceptor agonist whose toxicity may cause clinical effects including sedation, respiratory depression and coma, bradycardia and hypotension and hyperglycaemia. Ventricular arrhythmia have also been reported.
Treatment should be supportive with appropriate intensive therapy.

4.6 Adverse reactions (frequency and seriousness)

4.7 Use during pregnancy, lactation or lay

4.8 Interaction with other medicinal products and other forms of interaction

Analeptics (stimulants) will shorten the period or reduce the depth of sedation. In horses and dogs, a deeper sedation with less side effects is achieved when Xylapan is combined with strong analgesics.

Horses
The concurrent intravenous use of potentiated sulphonamides with alpha-2 agonists has been reported to cause cardiac arrhythmia which may be fatal. It is recommended that intravenous administration of trimethoprim/ sulphonamide containing products should not be undertaken when horses have been sedated with Xylapan.
Limited information available indicates that alpha/2 blockers such as atipamazole may be effective in reversing the sedation and other physiological effects of the drug.

4.9 Amounts to be administered and administration route

Syringes and needles need to be sterilised before use. Clean area of injection site and swab with spirit.
It should be noted that dosage and routes of administration vary widely between species.
An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important with injecting small volumes.

Cattle
Xylapan is given by intramuscular injections taking precautions against contamination.

The dose is 0.05-0.3 mg / kg bodyweight xylazine (0.25 to 1.5 ml Xylapan per 100 kg body weight) according to the degree of sedation required. Very fractious animals may require the higher dose rate, not exceeding 0.3 mg / kg (Dose rate 4):

Dose	mg / kg	ml / 50kg
1	0.05	0.125
2	0.10	0.25
3	0.20	0.50
4	0.30	0.75

The degree of sedation can be predetermined according to the dose administered.
Dose 1: Sedation with slight decrease of muscle tone. The ability to stand is maintained.
Dose 2: Sedation, marked decrease of muscle tone and some analgesia. The animal usually remains standing but may lie down.
Dose 3: Deep sedation, further decrease of muscle tone and a degree of analgesia. The animal lies down.

Dose 4: Very deep sedation, a profound decrease of muscle tone and a degree of analgesia. The animal lies down.
After doses 3 & 4 cattle are likely to remain drowsy for several hours and should be kept in the shade.
The animal should not be disturbed until Xylapan has taken its full effect. The first effects are usually seen within five minutes of first injection and the maximum effect is produced 10 minutes later. There is no struggling or excitement during induction or recovery.
If the required depth of sedation is not achieved, it is unlikely that repetition of the dose will prove more effective. It is advisable to allow complete recovery, repeating the procedure with a higher dose after 24 hours.
For any surgical treatment carried out Xylapan, additional local anaesthesia should be employed.

Horses
Xylapan is given by slow intravenous injection, taking from one to two minutes.
Dosage depends upon the degree of sedation required and the response of the animal and is 0.6-1.0 mg / kg bodyweight (3-5 ml / 100 kg bodyweight).
Nervous or highly excitable horses generally require the higher dose.
Experience has shown that older horses and those that have undergone severe physical exertion before treatment respond more readily to Xylapan.
Depending on the dosage, light to deep sedation with individually variable analgesia is obtained. The horse does not become recumbent.
Animals should not be disturbed until Xylapan has taken its full effect. This is usually within five minutes of intravenous injection and lasts for approximately 20 minutes.
If the required depth of sedation is not achieved, it is unlikely that repetition of the dose will prove more effective. It is advisable to allow complete recovery, repeating the procedure using Xylapan at a higher dose rate after 24 hours.
For painful operations, additional local or regional anaesthesia should be used.
Xylapan can also be administered to horses as premedication for operations of the recumbent animal using chloral hyfrate, barbiturates, ketamine or halothane.

Cats
Xylapan is given intramuscularly at a dose rate of 3.0 mg / kg (0.15 ml / kg).
The effect is adequate for procedures that are not associated with any considerable degree of pain.
Premedication with atropine is advantageous.
When used in conjunction with ketamine, Xylapan premedication eliminates muscular stiffness during anaesthesia and maintains sedation throughout the recovery period.
Barbiturate anaesthesia should not be induced until sedation is deepest, i.e. about 20 minutes after administration of Xylapan. Under these conditions, the dose of barbiturate required is reduced by about half.

Dogs
Xylapan is given intramuscularly at a dose rate of 1-3 mg / kg (0.05 – 0.15 ml / kg).
Other routes of administration may be used by the effect is less predictable.
Good sedation is usually achieved at the lower end of the dose range given above, but excitable or vicious animals require a larger dose. The effect is adequate for procedures that are not associated with any considerable degree of pain.

For painful procedures, Xylapan may be used in combination with a local anaesthetic.
Premedication with atropine may be advantageous.
When used for pre-anaesthetic medication, Xylapan reduces the dose required, in the case of barbiturates, by about a half.
Xylazine can be used as a premedicant for ketamine induced anaesthesia.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In the case of accidental overdose leading to respiratory failure, cold water douches and artificial respiration are indicated.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: One day
Milk: Zero hours

Horses:
Meat and offal: One day

ATC vet code: QN05C M92

6.1 Pharmaceutical precautions

Following withdrawal of the first dose use the product within 12 days. Discard unused material. Avoid introduction of contamination.

Do not store above 25^{o}C.
When the container is broached for the first time, using the in-use shelf-life which is specified on this package insert, 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/ carton.
Do not use after the expiry date stated on the label. Keep the container in the outer carton.

6.5 Package Quantities

10ml vials
50ml vials

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials

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

6. MARKETING AUTHORISATION HOLDER

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7. MARKETING AUTHORISATION NUMBER

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8. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

OTHER INFORMATION:

Legal category
POM-V
To be supplied only on veterinary prescription.
For animal treatment only.
Keep out of reach of children.

Gavin Hall
Approved: 05 December 2025