PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rompun 2% w/v Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 23.32 mg xylazine hydrochloride (equivalent to 20 mg xylazine) as active substance and 1.5 mg methyl 4-hydroxybenzoate as preservative.

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

25 ml

5. TARGET SPECIES

Cattle, horses, dogs, cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See leaflet for full instructions.

8. WITHDRAWAL PERIOD

WITHDRAWAL PERIODS

Cattle (Meat): 1 day.

Cattle (Milk): Zero hours.

Horse (Meat): Not to be used in horses intended for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Operator warnings

Alpha-2-adrenoreceptor agonists can cause severe adverse reactions. You must read the operator warnings on the package leaflet before using this product.

10. EXPIRY DATE

Exp.: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
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

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

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
D-27472 Cuxhaven
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 52127/5078

17. MANUFACTURER’S BATCH NUMBER

Batch no.: {number}

Manufactured by: KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, D-24106 Kiel, Germany

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rompun 2% w/v Solution for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains 23.32 mg xylazine hydrochloride, equivalent to 20 mg xylazine.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

25 ml

4. ROUTE(S) OF ADMINISTRATION

See leaflet for full instructions.

5. WITHDRAWAL PERIOD

WITHDRAWAL PERIODS

Cattle (meat): 1 day

Cattle (milk): Zero hours

Horse (meat): Not to be used in horses intended for human consumption

6. BATCH NUMBER

Batch No.: {number}

7. EXPIRY DATE

Exp.: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

KEEP OUT OF REACH OF CHILDREN.

Do not store above 25°C. Discard unused product.

Following withdrawal of the first dose, use product within 28 days.

Discard date: …..……../……./…….

UK only

Vm 52127/5078

POM-V

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
D-27472 Cuxhaven
Germany

Authorised Veterinary Medicinal Product.

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

PACKAGE LEAFLET FOR: ROMPUN 2% w/v SOLUTION FOR INJECTION

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

MA Holder:

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
D-27472 Cuxhaven
Germany

Manufacturer responsible for batch release:

KVP Pharma und Veterinär Produkte GmbH, Projensdorfer Str. 324, 24106 Kiel, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rompun 2% w/v Solution for Injection

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

A clear, colourless, aqueous solution for injection. Each ml contains 23.32 mg xylazine hydrochloride (equivalent to 20 mg xylazine) as active substance and 1.5 mg methyl 4-hydroxybenzoate as preservative.

4. INDICATION(S)

Uses:
Xylazine is an alpha-2-agonist with sedative, some analgesic 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: All cases where sedation is required including:
1) Handling fractious animals e.g. for transportation.
2) Medical examination e.g. x-ray examination, removal of bandages, examination of teats, penis and oral cavity.

3) Pre-medication for minor superficial operations, painful manipulative procedures and local or regional anaesthesia

5. CONTRAINDICATIONS

Do not use in the latter stages of pregnancy except at 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**.**

In the cat and dog, because of the emetic effect which is sometimes produced, Rompun should not be used in mechanical complications of the alimentary tract such as obstruction of the oesophagus, gastric torsion or hernia.

6. ADVERSE REACTIONS

Not applicable

7. TARGET SPECIES

Cattle, Horses, Dogs, Cats

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

Dosage and administration

Read the operator warnings before using this product.

Cattle: Rompun is given by intramuscular injection. The dose rate is 0.05-0.3 mg/kg (0.25-1.5 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 (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	0.50
4	0.30	15.0	0.75

Dose 1	Sedation with a 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 in muscle tone and a degree of analgesia. The animal lies down

Animals should not be disturbed until Rompun has taken its full effect. The first effects are usually seen within 5 minutes of injection and the maximum effect is produced ten 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.

When any surgical treatment is carried out using Rompun, additional local anaesthesia should be employed.

Horses:

Rompun 2% solution is given by slow intravenous injection, taking from one to two minutes to administer. Dosage depends on the degree of sedation required and the response of the animal and is 0.6-1 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 exertion before treatment respond more readily to Rompun.

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 Rompun has taken its full effect. This is usually obtained within 5 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 Rompun Dry Substance, with a higher dose rate, after 24 hours.

For operations and painful procedures, additional local or regional anaesthesia should be used.
Rompun can also be administered to horses as a pre-medicant for operations on the recumbent animal using chloral hydrate, barbiturates, ketamine or halothane.

Cats:

Rompun 2% solution is given intramuscularly at a dose rate of 3 mg/kg (0.15 ml/kg) bodyweight. The effect is adequate for procedures that are not associated with any considerable degree of pain. Pre-medication with atropine is advantageous.

When used in conjunction with ketamine, Rompun pre-medication eliminates muscular stiffness during anaesthesia and maintains sedation throughout the recovery period.

Barbiturate anaesthesia should not be induced until sedation is at its deepest, i.e. about 20 minutes after administration of Rompun. Under these conditions the dose of barbiturates is reduced by about half.

Dogs:

Rompun 2% solution is given by intramuscular injection at a dose rate of 1-3 mg/kg (0.05-0.15 ml/kg) bodyweight. Other routes of administration may be used, but 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 higher dose. The effect is adequate for procedures that are not associated with any considerable degree of pain. For painful procedures, Rompun may be used in combination with a local anaesthetic.

Pre-medication with atropine may be advantageous. When used for pre-anaesthetic medication, Rompun reduces the dose required in the case of barbiturates by about half. Rompun can also be used as a pre-medicant for ketamine induced anaesthesia.

9. ADVICE ON CORRECT ADMINISTRATION

Syringes and needles must be sterile. Clean area of injection site and swab with spirit.

10. WITHDRAWAL PERIOD(S)

Protection of Consumers:

Animals must not be slaughtered for human consumption during treatment.

Cattle:	Meat:	1 day.
Cattle:	Milk:	Zero hours.

Horse: 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.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Discard unused material. Discard vial if visible contamination occurs. When the container is broached (opened) for the first time, the date on which any product remaining in the container should be discarded should be calculated. A statement of the in-use shelf life of this product is given below. This discard date should be written in the space provided on the label. Following withdrawal of the first dose, use the product within 28 days.

KEEP OUT OF REACH OF CHILDREN.

12. SPECIAL WARNING(S)

FOR ANIMAL TREATMENT ONLY.

Caution is required when pulmonary disease is present of suspected.
Use with care in elderly or debilitated animals which may be adversely affected by profound cardiovascular changes.
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 or ruminal fluids. When high doses are to be employed, the animal should be fasted for some hours beforehand. It must be noted that the swallowing reflex is reduced during the period when the action of the drug is at its peak.
Concurrent usage of other adrenoceptor stimulants should be avoided.
After dose levels 3 and 4 cattle are likely to remain drowsy for several hours and should be kept in the shade.
In case of accidental overdosage leading to respiratory failure, cold water douches and artificial respiration are indicated.
Following intravenous injection in horses there is a transient rise followed by a fall in blood pressure.
With horses, the usual precautions required for handling should always be observed even when a high dose of Rompun has been given.
The concurrent intravenous use of potentiated sulphonamides with alpha-2 agonists has been reported to cause cardiac arrhythmias which may be fatal. Whilst no such effects have been reported with Rompun, it is recommended

that intravenous administration of trimethoprim/sulphonamide containing products should not be undertaken when horses have been sedated with Rompun.
In cats and dogs if the stomach is full, 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 to 24 hours. In the event of respiratory failure manual compression of the thorax is usually sufficient to restore normal respiration.

Sedated animals should remain under observation until normal. They should be segregated to avoid bullying by others.
Analeptics will shorten the period or reduce the depth of sedation.
Alpha-2-blockers such as atipamezole may be effective in reversing the sedation and other physiological effects of the drug,
Transient hyperglycaemia is a common finding after Rompun sedation.

Operator Warnings:

Care should be taken to avoid accidental self-injection. To avoid accidental self-injection, one of the following procedures should be adopted. Either use two sterile needles, one to fill syringe from bottle and one to inject patient, or once the required dose has been withdrawn from the vial, immediately remove the needle from the syringe, insert the needles into the injection site, and then connect the syringe to it. Used needles should be safely deposited in a closed container.

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 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 alpha-2-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.

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

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

14. 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.

15. OTHER INFORMATION

UK Authorised Veterinary Medicinal Product

POM-V	UK only Vm 52127/5078

To be supplied only on veterinary prescription

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
D-27472 Cuxhaven
Germany

Manufactured by: KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Str. 324, D-24106 Kiel, Germany

Approved 28 March 2025
Gavin Hall