SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rompun 2% w/v Solution for Injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s)

Xylazine hydrochloride	2.332g/100ml (equivalent to 2.0g/100ml xylazine base)

Excipients

Methyl hydroxybenzoate (E218)	0.150g/100ml

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses, dogs and cats.

4.2 Indications for use, specifying the target species

Sedative with some analgesic and muscle relaxant properties for use in cattle, horses, dogs and cats.

All cases where sedation is required including:

i) Handling fractious animals (e.g. for transportation).

ii) Medical examination e.g. X-ray examination, removal of bandages, examination of teats, penis and oral cavity.

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

4.3 Contra-indications

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, do not use xylazine in mechanical complications of the alimentary tract e.g. obstruction of the oesophagus, gastric torsion or hernia.

4.4 Special warnings for each target species

Applicable to all species

Use with care in elderly or debilitated patients which may be adversely affected by profound cardiovascular changes.

Cattle

Tympany should be prevented in recumbent cattle by sternal recumbency.

For operations in lateral or dorsal recumbency, lower head and neck to prevent inhalation of ruminal contents.

Maintain recumbent and drowsy animals in the shade. In case of accidental overdosage leading to respiratory failure, cold water douches and artificial respiration are indicated.

After dose levels 3 and 4 cattle are likely to remain drowsy for several hours and should be kept in the shade.

Horses

Following intravenous injection in horses a transient rise and fall of blood pressure may be seen.

With horses the usual precautions required in handling should always be observed even when a high dose of xylazine has been given.

Dogs and cats

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.

Pre-medication with atropine in cats and dogs may reduce salivation and bradycardia effects.

4.5 Special precautions for use

i. Special precautions for use in animals

Caution is required when pulmonary disease is present.
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.
Sedated animals should remain under observation until normal.
Segregate sedated animals.
In the event of respiratory failure manual compression of the thorax is usually sufficient to restore normal respiration.
Observe aseptic precautions.

ii. Special precautions to be taken by the person administering the medicinal product to animals

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 mucoal contact.
3. Immediately after exposure, wash the exposed sking with large amounts of fresh water.
4. Remove contaminated clothes that are in direct contacat 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 aplha2-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)

Not applicable.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of adrenoceptor stimulants is not recommended. 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 xylazine.

4.9 Amounts to be administered and administration route

Use two sterile needles, one to fill the syringe from the bottle and one to inject the patient. Once the required dose has been withdrawn from the vial, the syringe should be removed from the needle. A separate sterile needle should be inserted into the injection site and the syringe connected to it. The needles should be discarded into a closed container.

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

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	0.50
4	0.30	15	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 the drug has taken its full effect. The first effects are usually seen within 5 minutes of 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.

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

Horses

Administer 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 the drug 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

Administer 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, xylazine 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

Administer 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, use in combination with a local anaesthetic. Pre-medication with atropine may be advantageous.

When used for pre anaesthetic medication, xylazine reduces the dose required in the case of barbiturates by about half. Xylazine can also be used as a pre-medicant for ketamine induced anaesthesia.

Further information applicable to all species

Analeptics will shorten the period or reduce the depth of sedation.
Limited information available suggests that 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 xylazine sedation.

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

Alpha$_2$-adrenoceptor blockers may reverse the effects.

4.11 Withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero

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.

5. PHARMACOLOGICAL/IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nervous system, hypnotics and sedatives

ATC vet code: QN05 CM92

Xylazine is an alpha-2 agonist with sedative, some analgesic and muscle relaxant properties, for use in cattle, horses, dogs and cats. In cattle, which are

more sensitive to the agent, the degree of sedation can be predetermined according to the dose administered. A strong emetic effect is usual in cats and dogs. Xylazine induces strong cardiovascular effects e.g. bradycardia and increased blood pressure. Hyperglycaemia is also induced.

5.2 Pharmacokinetic particulars

The duration of action of the agent varies between species.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl-4-hydroxybenzoate
Sodium chloride
Sodium carbonate
Water for Injections

6.2 Major incompatibilities

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 xylazine, it is recommended that intravenous administration of Trimethoprim/Sulphonamide containing products should not be undertaken when horses have been sedated with Rompun.

6.3 Shelf life

Shelf life of product:	3 years
Shelf life after reconstitution:	Not applicable
Shelf after opening package:	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

A clear, colourless, sterile, aqueous solution of Xylazine hydrochloride (2.332% w/v) for parenteral administration in cattle, horses, dogs and cats.

25ml clear glass flint type II glass vial with a siliconised chlorobutyl rubber bung and secured with an aluminium and polypropylene overseal.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

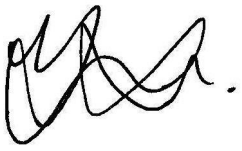
Vm 00879/4159

9. DATE OF FIRST AUTHORISATION

14 December 1995

10. DATE OF ANY REVISION OF THE TEXT

September 2020



Approved: 17 September 2020