NOAH Compendium

Bayer plc
Telephone: 0118 206 3000
Website: www.bayer.co.uk
Email: animal.health@bayer.com

Rompun 2% w/v Solution for Injection

Species:	Cats, Cattle, Dogs, Horses and other equidae
Therapeutic indication:	**Pharmaceuticals: Neurological preparations:** Tranquilisers
Active ingredient:	Xylazine Hydrochloride
Product:	Rompun® 2% w/v Solution for Injection
Product index:	Rompun 2% w/v Solution for Injection
Cattle - milk:	Zero hours
Cattle - meat:	1 day
Withdrawal notes:	Do not use in horses intended for human consumption

Presentation

A clear colourless sterile aqueous solution for injection. Each ml contains 23.32 mg xylazine hydrochloride (equivalent to 20 mg xylazine) with 1.5 mg methyl hydroxybenzoate (E218) as excipient.

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, which are more sensitive to the agent, 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 examinations, e.g. x-ray examination, removal of bandages, examination of teats, penis and oral cavity.

3) Premedication for minor superficial operations, painful manipulative procedures and local or regional anaesthesia.

Printed from NOAH Compendium (http://www.noahcompendium.co.uk). (c) Copyright NOAH Compendium 2020. All Rights Reserved.
Date: Thursday, January 30, 2020 16:23

Dosage and administration

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 Once the required dose has been withdrawn from the vial, the syringe should be removed from the needle.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 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) body weight, 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 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 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 (3–5 ml/100 kg) body weight. 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 xylazine.

Depending on the dosage, light to deep sedation with individually variable analgesia is obtained. The horse does not become recumbent.

Printed from NOAH Compendium (http://www.noahcompendium.co.uk). (c) Copyright NOAH Compendium 2020. All Rights Reserved.
Date: Thursday, January 30, 2020 16:23

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 premedicant 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) body weight. 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, xylazine premedication 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) body weight. 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. Premedication with atropine may be advantageous.

When used for pre-anaesthetic medication, xylazine reduces the dose required in the case of barbiturates by about half. Rompun can also be used as a premedicant 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.

Use During Pregnancy and Lactation

Printed from NOAH Compendium (http://www.noahcompendium.co.uk). (c) Copyright NOAH Compendium 2020. All Rights Reserved.
Date: Thursday, January 30, 2020 16:23

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.

Contra-indications, warnings, etc

All Species

Observe aseptic precautions.

When high doses are to be employed the animal should be fasted for some hours beforehand.

Sedated animals should remain under observation until normal. Segregate sedated animals.

Concurrent administration of adrenoceptor stimulants is not recommended.

It must be noted that the swallowing reflex is reduced during the period when the action of the drug is at its peak.

In the event of respiratory failure manual compression of the thorax is usually sufficient to restore normal respiration.

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

Caution is required when pulmonary disease is present.

In the case of overdosage alpha$_2$-adrenoceptor blockers may reverse the effects.

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 in 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.

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 xylazine.

Dogs and Cats

Printed from NOAH Compendium (http://www.noahcompendium.co.uk). (c) Copyright NOAH Compendium 2020. All Rights Reserved.
Date: Thursday, January 30, 2020 16:23

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 beforehand.

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.

Premedication with atropine may reduce salivation and bradycardia effects.

User Safety

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 needle 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.

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.

Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment.

Cattle: Meat: 1 day, Milk: Zero hours

Horse (meat): Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.

Printed from NOAH Compendium (http://www.noahcompendium.co.uk). (c) Copyright NOAH Compendium 2020. All Rights Reserved.
Date: Thursday, January 30, 2020 16:23

The horse must have been declared as not intended for human consumption under national horse passport legislation.

Environmental Safety

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

Pharmaceutical precautions

Do not store above 25°C.

Following withdrawal of the first dose use the product within 28 days. Discard unused material.

Shelf life of product: 3 years

Shelf after opening package: 28 days

Shelf life after reconstitution: Not applicable

Legal category

Legal category: POM-V

Packaging quantities

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

Further information

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.

The duration of action of the agent varies between species.

In the case of overdosage alpha$_2$-adrenoceptor blockers may reverse the effects.

Marketing Authorisation Number

Vm 00010/4093

Printed from NOAH Compendium (http://www.noahcompendium.co.uk). (c) Copyright NOAH Compendium 2020. All Rights Reserved.
Date: Thursday, January 30, 2020 16:23

NOAH Compendium

Significant changes

GTIN

GTIN description: Rompun 2% w/v Solution for Injection (25ml)

GTIN: 05032756093017

Printed from NOAH Compendium (http://www.noahcompendium.co.uk). (c) Copyright NOAH Compendium 2020. All Rights Reserved.
Date: Thursday, January 30, 2020 16:23