SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rompun Dry Substance
500 mg Powder and Solvent for Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	**mg per vial**
Xylazine	500
(as Xylazine hydrochloride	583)

Relevant Constituents of the Excipients

Solvent for use with Rompun Dry Substance is Water for Injection 10 ml per vial.

For full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, Zoo animals

4.2 Indications for use, specifying the target species

For use in horses and zoo animals 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. Pre-medication for minor superficial operations, painful manipulative procedures and local or regional anaesthesia.

4.3 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.

4.4 Special warnings for each target species

Caution is required when pulmonary disease is present or suspected. In recumbent ruminants, tympany should be prevented by maintaining sternal recumbency. For operations on ruminants in lateral or dorsal recumbency it is advisable to lower the head and neck in order to avoid inhalation of saliva or ruminal fluids. Following intravenous injection in horses, there is a transient rise followed by a fall in blood pressure.

Transient hyperglycaemia is a common finding after Rompun sedation.

4.5 Special precautions for use

i. Special precautions for use in animals

With horses and zoo animals the usual precautions required for handling should always be observed even when a high dose of Rompun has been given.

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

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use two sterile needles, one to fill syringe from bottle and one to inject patient, or once the required dose has been withdrawn from the vial, immediately remove the needle from the syringe, insert the needle into the injection site, and then connect the syringe to it.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 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 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.

iii. Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

The swallowing reflex is reduced during the period when the action of the drug is at its peak.

After high doses animals are likely to remain drowsy for several hours and should be kept in the shade.

Following intravenous injection in horses, there is a transient rise followed by a fall in blood pressure.

Transient hyperglycaemia is a common finding after Rompun sedation.

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

Analeptics will shorten the period or reduce the depth of sedation. Alpha-2 blockers such as atipamezole are effective in reversing the sedation and other physiological effects of the drug.

4.9 Amount(s) to be administered and administration route

Rompun Dry Substance is dissolved in the solvent provided and given by intramuscular or intravenous injection in the horse and intramuscular injection only in zoo animals. Intravenous injection in the horse should be slow, taking from one to two minutes to administer. Syringes and needles must be sterile. Clean the area of injection site and swab with spirit.

Method of Administration

To avoid accidental self-injection, the following procedure should be adopted. Use two sterile needles, one to fill syringe from bottle and one to inject the patient. Once the required dose has been withdrawn from the bottle, 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.

Dissolving one bottle of Rompun Dry Substance in 10 ml of solvent yields a 5% (50 mg/ml) solution, and in 5 ml yields a 10% (100 mg/ml) solution.

Horse

	mg/kg	ml 5% solution per 50 kg bodyweight	ml 10% solution per 50 kg bodyweight
Intravenous	0.6-1.0	0.6-1.0	0.3-0.5
Intramuscular	2.4-3.0	2.4-3.0	1.2-1.5

Intravenous injection should be slow taking 1-2 minutes.

These dosages are effective in most cases.

Dosage depends on the degree of sedation required and the response of the animal. Nervous or highly excitable horses generally require a slightly higher dose. Experience has shown that older horses and those that have undergone sever 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. If it is desirable to achieve the maximum possible sedation, the intramuscular route and the highest dose rate are recommended.

Animals should not be disturbed until Rompun has taken its full effect. This is usually obtained within 5 minutes of intravenous injection and 15 minutes of intramuscular injection. Sedation lasts 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 after 24 hours using a higher dose rate.

For operations and painful procedures, additional local or regional anaesthesia should be used.

Zoo Animals

The dose rates required are variable. Veterinary surgeons are advised to contact the company prior to use in species other than those shown below.

	mg/kg	ml 5% solution per 10 kg bodyweight	ml 10% solution per 10 kg bodyweight
Roe deer (*Capreolus capreolus*)	2-3	0.4-0.6	0.2-0.3
Red deer (*Cervus elaphus*)	2-3	0.4-0.6	0.2-0.3
Fallow deer (*Dama dama*)	6-8	1.2-1.6	0.6-0.8

Before zoo animals are approached after treatment, 20 minutes should be allowed to elapse. Full sedation will last approximately 30 minutes. It should not be assumed that the animal is fully sedated and personal precautions should never be neglected.

Rompun Dry Substance can be used to control cattle destined for slaughter under the Bovine Spongiform Encephalopathy Order.

Sedated or immobilised animals should remain under supervision until normal. They should be segregated to avoid bullying by others.

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

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

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

4.11 Withdrawal period(s)

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.
Zoo Animals:	Contra-indicated for animals intended for human consumption

5. PHARMACOLOGICAL PROPERTIES

Xylazine, 5, 6-dihydro-2-(2,6-xylidino)-4H-1,3-thiazine, is a thiazine derivative with sedative, hypnotic, local anaesthetic and hypotensive properties. It also has muscle relaxant and analgesic effects; the degree of relaxation/analgesia depends upon the animal species.

ATC Vet Code: QN05CM92

5.1 Pharmacodynamic properties

Xylazine is an agonist of the alpha-2 adrenergic receptors. It acts on pre-synaptic and post-synaptic receptors of the central and peripheral nervous system. Both the sedation and the analgesia are due to stimulation of central alpha-2 adrenergic receptors.

5.2 Pharmacokinetic particulars

Xylazine is absorbed extremely rapidly and distributed widely throughout tissues. After intramuscular injection maximum plasma concentrations are achieved within 12-14 minutes in all species.

Bioavailability varies after intramuscular injection; in the dog it is between 52 and 90%, in the sheep. 17-73% and in the horse 40-48%. Metabolism is extremely rapid. The molecule is broken down into several metabolites. Elimination after intramuscular and intravenous application takes place with a half-life of between

23 and 60 minutes depending on species. The half-life for total elimination, which is dependant on the route administration and dosage, is 2-3 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder Component: None

Solvent: Water for Injection

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf-life of the product as packaged for sale: 5 years

Shelf-life after dilution or reconstitution: Zero days

Shelf-life after first opening the container: Zero days

6.4 Special precautions for storage

Product as packaged for sale: Do not store above 25^{o}C.
Store in a dry place.

Reconstituted product: Reconstitute immediately before use. Any solution remaining in the vial following withdrawal of the required dose should be discarded.

Solvent vial: Any solution remaining in the vial following withdrawal of the required dose should be discarded.

6.5 Nature and composition of immediate packaging

Container material: Type II glass

Container closure: Grey butyl rubber bung

Container colour Clear colourless

Container volumes 5 vials each containing 500 mg xylazine hydrochloride (powder); 5 vials each containing 10 ml (solvent)

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Bayer plc,
Animal Health Division,
Bayer House,
Strawberry Hill,
Newbury,
Berkshire RG14 1JA

8. MARKETING AUTHORISATION NUMBER(S)

Vm 00010/4092

9. DATE OF FIRST AUTHORISATION

Date: 20 August 1993

9.1 Last Renewal of the Authorisation

Date: 20 August 2003

10. DATE OF LAST REVISION OF THE TEXT

June 2011