SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquinervin 10 mg/ml solution for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active substance:
Acepromazine 10 mg
(equivalent to 13.55 mg acepromazine maleate)

Excipients:
Phenol 3.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow to orange solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

Anaesthetic Premedication: Following acepromazine administration, the amount of anaesthetic necessary to induce anaesthesia is considerably reduced.

Tranquilisation: Acepromazine tranquilisation (ataraxy) involves a modification of temperament which is not associated with hypnosis, narcosis or marked sedation. This is achieved with low doses of acepromazine. At low doses, acepromazine reduces anxiety which is beneficial for use in horses prior to shoeing or transportation.

Sedation: At higher dose rates acepromazine is an effective sedative, as an adjunct to, or replacement for, physical restraint e.g. dentistry, handling and shoeing. The relaxant effects aid examination of the penis in horses and the treatment of tetanus and choke.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer to breeding stallions. See section 4.6.
Do not use in pregnant mares.
Do not use in animals in existing severe emotional excitation.

4.4 Special warnings for each target species

Acepromazine has little, if any, analgesic effect so that painful procedures must be avoided, particularly where animals are known to have unpredictable temperaments. Therefore, the usual precautions should be maintained when handling sedated horses. During sedation, horses will normally retain visual and auditory acuity, so that loud sounds and rapid movements may cause arousal from the sedated state. It is therefore important to keep treated horses in a quiet environment and avoid sensory stimulation as far as possible.

4.5 Special precautions for use

Special precautions for use in animals
Situations may arise where general anaesthesia is required in the 4−6 hours following use of the product. In such cases care should be taken to reduce the dose of other premedicants and anaesthetic agents, particularly parenteral barbiturates, so as to avoid potentiation and additive depressant effects.
When administered to male horses (geldings or non-breeding stallions), use the lowest dose recommended to produce the required effect.
Acepromazine may cause hypothermia due to depression of the thermoregulatory centre and peripheral vasodilation.
Acepromazine is an adrenoceptor blocking drug and this causes hypotension and lowered haematocrit. The product should therefore be administered with great caution, and at low dose rates only to debilitated horses and animals in states of hypovolaemia, anaemia and shock, or with cardiovascular disease. Rehydration should precede acepromazine administration.
Duration of action may be prolonged and this should be remembered when riding, as acepromazine may affect performance and appear in drug tests for some time.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product contains a potent sedative; care should be taken, when handling and administering the product, to avoid accidental self-exposure.
In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur. Symptomatic treatment may be required.
If accidental eye contamination occurs, flush gently with fresh running water for 15 minutes. Medical advice should be sought if irritation persists.
In the event of accidental skin contamination, contaminated clothing should be removed and the area washed with large amounts of soap and water. Medical advice should be sought if irritation persists.
Wash hands and exposed skin thoroughly after use.

4.6 Adverse reactions (frequency and seriousness)

Acepromazine may cause hypotension (common) and lowered haematocrit (very common). Reversible paralysis of the retractor penis muscle has been associated with the use of parenterally administered acepromazine in horses (very common). Acepromazine has caused paraphimosis (uncommon), sometimes as a sequel to priapism, however this only very rarely results in permanent penile dysfunction. When extrusion of the penis occurs, the owner should be advised to inform his veterinary surgeon if retraction of the penis does not take place within 2−3 hours. Suitable treatments have been described in the veterinary literature e.g. manual compression during the period of general anaesthesia, penile support and manual compression, use of an Esmarch bandage, or drug reversal (e.g. slow intravenous administration of benztropine mesylate).
Accidental intracarotid injection in horses can produce clinical signs ranging from disorientation to convulsive seizures and death.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals is 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant mares. The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Phenothiazines are additive to the actions of other CNS depressants and will potentiate general anaesthesia (see section 4.2, indications for use).
Do not use this product in conjunction with organophosphates and/or procaine hydrochloride, as it may enhance activity and potential toxicity.

4.9 Amounts to be administered and administration route

For intramuscular or intravenous injection. In case of intravenous injection, it is recommended the injection is made slowly.

0.03−0.10 mg acepromazine per kg bodyweight, equivalent to 0.15−0.5 ml product per 50 kg bodyweight.

Normally, single doses of acepromazine are administered. Long term use is not recommended. On the rare occasions that repeat dosing is required, the dosing interval should be 36−48 hours.
Take adequate precautions to maintain sterility. Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, discard the product.
The maximum number of vial punctures when using needle sizes of 21G and 23G should not exceed 100 and when using a 18G needle, the maximum should not exceed 40.

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

Transient dose-dependent hypotension may occur in cases of accidental overdose. Therapy should consist of discontinuing any other hypotensive treatment, supportive care such as intravenous infusion of warm isotonic saline to correct hypotension and close monitoring. In severe cases treatment with norepinephrine may be indicated but its use must be based on a careful evaluation of the benefit risk balance by the responsible veterinary surgeon.
Epinephrine (adrenaline) is contra-indicated in the treatment of acute hypotension produced by overdosage of acepromazine maleate, since further depression of systemic blood pressure can result.

4.11 Withdrawal period(s)

The product is not authorised for use in horses intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antipsychotics
ATCvet code: QN05AA04

5.1. Pharmacodynamic properties

Acepromazine is a phenothiazine. It is a central nervous system depressant with associated activity on the autonomic system. Phenothiazines have a central action due to inhibition of dopamine pathways, resulting in alteration of mood, reduction in fear and removal of learned or conditioned responses.
Acepromazine possesses anti-emetic, hypothermic, vasodilatory (and therefore hypotensive) and anti-spasmodic properties.

5.2 Pharmacokinetic particulars

The length of action of acepromazine appears to be prolonged and to be dose dependent.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium hydroxide (for pH adjustment)
Maleic acid (for pH adjustment)
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after opening of the immediate packaging: 56 days.

6.4 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Clear type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box.
Pack sizes: 10 ml, 20 ml, and 100 ml.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 41821/4054

9. DATE OF FIRST AUTHORISATION

09 April 2018

10. DATE OF REVISION OF THE TEXT

July 2022

Approved 12 July 2022