ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Outer carton
Glass vials of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquinervin 10 mg/ml solution for injection for horses
acepromazine

2. STATEMENT OF ACTIVE SUBSTANCES

Acepromazine 10 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
20 ml
100 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous or intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 56 days
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
Supply / use: (National issue)

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41821/4054

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vials of 10 or 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquinervin 10 mg/ml solution for injection for horses
acepromazine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

10 mg/ml

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

10 ml
20 ml

4. ROUTE(S) OF ADMINISTRATION

IV, IM

5. WITHDRAWAL PERIOD(S)

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

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 56 days
Once broached use by ……..

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Tranquinervin 10 mg/ml solution for injection for horses

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

Marketing authorisation holder:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquinervin 10 mg/ml solution for injection for horses
acepromazine

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

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

Excipients:
Phenol (preservative) 3.0 mg

Clear yellow to orange solution.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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 (condition where the foreskin of the penis is trapped behind the glans penis; uncommon), sometimes as a sequel to priapism (condition where the penis remains erect in the absence of stimulation), 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)

If you notice any side effects, even those not already listed in this package leaflet or if you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 56 days

12. SPECIAL WARNING(S)

For the animal owner:
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 warnings for each target species:
For the veterinarian:
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.

Special precautions for use in animals:
For the veterinarian:
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.

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 leaflet or the label to the physician but DO NOT DRIVE as sedation may occur. Symptomatic treatment may be required.
If accidental eye contact occurs, flush gently with fresh running water for 15 minutes and seek medical advice if any irritation persists.
In the event of accidental skin contact, 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.

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

Overdose (symptoms, emergency procedures, antidotes):
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.

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

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD-MM-YYYY

15. OTHER INFORMATION

Pack sizes:
10 ml, 20 ml or 100 ml.
Not all pack sizes may be marketed.

Approved 12 July 2022