ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Outer carton: Single pack outer carton and multi-pack outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquigel 35 mg/g oral gel for dogs and horses
acepromazine

2. STATEMENT OF ACTIVE SUBSTANCES

1 gram contains:
Acepromazine (as acepromazine maleate) 35.0 mg

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

3 gram
6 gram
10 gram
12 gram
12 x 3 gram
12 x 6 gram
12 x 10 gram
12 x 12 gram

5. TARGET SPECIES

Dogs and horses

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not authorised for use in horses intended for human consumption.

9. SPECIAL WARNING, IF NECESSARY

Acepromazine causes sedation and is DANGEROUS IF INGESTED. Replace push-fit cap immediately after use and return syringe to the original carton. READ ENCLOSED PACKAGE LEAFLET before use for full instructions and all warnings.

10. EXPIRY DATE

EXP:
Shelf-life after first opening the immediate packaging: 56 days (8 weeks).
Once broached use by: …….

11. SPECIAL STORAGE CONDITIONS

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.

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

Vm 41821/4044

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Container (pre-filled oral syringe)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquigel 35 mg/g oral gel
acepromazine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Acepromazine (as acepromazine maleate) 35.0 mg/g

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

3 gram
6 gram
10 gram
12 gram

4. ROUTE OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD(S)

Not authorised for use in horses intended for human consumption.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Once broached use by: ……..

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Tranquigel 35 mg/g oral gel for dogs and 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

Tranquigel 35 mg/g oral gel for dogs and horses
acepromazine

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 gram contains:

Active substances:
Acepromazine (as acepromazine maleate) 35.0 mg

Excipient(s):
Methyl parahydroxybenzoate (E 218) 1.04 mg
Propyl parahydroxybenzoate 0.104 mg

Clear, viscous, orange-yellow gel.

4. INDICATION

For sedation of dogs and horses

5. CONTRAINDICATIONS

Do not use in cases of hypotension, post-traumatic shock or hypovolemia.
Do not use in animals in a state of severe emotional excitation.
Do not use in animals suffering from hypothermia.
Do not use in animals with haematological disorders/coagulopathies or anaemia.
Do not use in animals with heart and or lung failure.
Do not use in animals with epilepsy.
Do not use in neonates.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Dogs
Hypotension (low blood pressure), tachycardia (increased heart rate), increase of respiratory rate, arrhythmia (irregular heart beat), miosis (contraction of the pupil), lacrimation and ataxia (incoordination). Contradictory clinical signs of aggressiveness and generalised CNS stimulation may occur.
Horses
Since acepromazine decreases sympathetic nervous system tone, a transient drop in blood pressure may occur after administration.
Inhibition of temperature regulation.
The following reversible changes are possible in the haemogram (results of a blood test):
- transient decrease in erythrocyte (red blood cell) count and haemoglobin concentration;
- transient decrease in thrombocyte (platelet) and leukocyte (white blood cell) counts.
Because acepromazine may increase prolactin secretion, the administration of acepromazine may lead to disturbances in fertility.
Penile prolapse may occur due to the relaxation of the retractor penis muscles. Retraction of the penis must be visible within two to three hours. If this does not take place, it is advised to contact a veterinary surgeon. Lack of retraction is of particular concern in breeding stallions. Administration of acepromazine has caused paraphimosis (the foreskin does not return to the normal position) sometimes in sequel to priapism (persistent erection).
Contradictory clinical signs of aggressiveness and generalised CNS stimulation may occur.
Prolapse of the nictitating membrane (third eyelid) has also been cited as a possible adverse effect in horses.

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

7. TARGET SPECIES

Dogs and horses

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

For oral use.
Dogs
Light sedation: 0.5 – 1.0 mg acepromazine / kg body weight (corresponding to 0.14 – 0.29 g of product per 10 kg body weight)
Deeper sedation: 1.0 – 2.0 mg acepromazine /kg body weight (corresponding to 0.29 – 0.57 g of product per 10 kg body weight)

Horses
Moderate sedation: 0.150 mg acepromazine / kg body weight (corresponding to 0.43 g of product per 100 kg body weight)
Deeper sedation: 0.225 mg acepromazine / kg body weight (corresponding to 0.64 g of product per 100 kg body weight)

The above dosage information is provided as a guideline and should be adapted to each patient, taking into account the various factors (e.g. temperament, breed, nervousness etc.) that may affect the sensitivity to sedatives.

Use of this veterinary medicinal product for light sedation in dogs weighing less than 17.5 kg should be based on a careful benefit: risk assessment by the responsible veterinarian. See also the section on **Special precautions for use in animals.**

The following tables are intended as a guide to dispensing this veterinary medicinal product at the recommended dose rates. Turn the dial ring anti-clockwise until the left side of the ring lines up with the weight of the oral gel to be administered.

Dogs Tranquigel

	Light Sedation 0.5 - 1.0 mg/kg body weight			**Deeper Sedation** 1.0 - 2.0 mg/kg body weight		
Body weight	**Dose of gel (gram)**	**Acepromazine (mg)**	**Dose range (mg/kg)**	**Dose of gel (gram)**	**Acepromazine (mg)**	**Dose range (mg/kg)**
10 kg – 17.5 kg	0.25	8.75	0.88 – 0.50	0.50	17.50	1.75 – 1.00
>17.5 kg – 20 kg	0.50	17.50	1.00 – 0.88	0.75	26.25	1.50 – 1.31
>20 kg – 25 kg	0.50	17.50	0.88 – 0.70	1.00	35.00	1.75 – 1.40
>25 kg – 30 kg	0.50	17.50	0.70 – 0.58	1.25	43.75	1.75 – 1.46
>30 kg – 40 kg	0.75	26.25	0.88 – 0.66	1.50	52.50	1.75 – 1.31
>40 kg – 50 kg	1.00	35.00	0.88 – 0.70	2.00	70.00	1.75 – 1.40
>50 kg – 60 kg	1.25	43.75	0.88 – 0.73	2.50	87.50	1.75 – 1.46
>60 kg – 70 kg	1.50	52.50	0.88 – 0.75	3.00	105.00	1.75 – 1.31

Horses Tranquigel

	Moderate Sedation 0.150 mg/kg body weight			**Deeper Sedation** 0.225 mg/kg body weight		
Body weight	**Dose of gel (gram)**	**Acepromazine (mg)**	**Dose range (mg/kg)**	**Dose of gel (gram)**	**Acepromazine (mg)**	**Dose range (mg/kg)**
100 kg – 150 kg	0.50	17.50	0.18 – 0.12	0.75	26.25	0.26 – 0.18
>150 kg – 200 kg	0.75	26.25	0.18 – 0.13	1.00	35.00	0.23 – 0.18
>200 kg – 250 kg	1.00	35.00	0.18 – 0.14	1.50	52.50	0.26 – 0.21
>250 kg – 300 kg	1.25	43.75	0.18 – 0.15	1.75	61.25	0.25 – 0.20
>300 kg – 350 kg	1.50	52.50	0.18 – 0.15	2.25	78.75	0.26 – 0.23
>350 kg – 400 kg	1.75	61.25	0.18 – 0.15	2.50	87.50	0.25 – 0.22
>400 kg – 500 kg	2.00	70.00	0.18 – 0.14	3.00	105.00	0.26 – 0.21
>500 kg – 600 kg	2.50	87.50	0.18 – 0.15	3.50	122.50	0.25 – 0.20

In dogs sedation usually sets in after 1 hour and lasts 8-12 hours, in horses sedations sets in after 15-20 minutes and lasts for 6-7 hours.
For longer use in dogs these doses may be repeated once after12 hours.

9. ADVICE ON CORRECT ADMINISTRATION

The 3 and 6 gram syringes have a dosage ring graduated every 0.25 gram.
The 10 and 12 gram syringes have a dosage ring graduated every 0.5 gram.
The most appropriate syringe should be chosen to ensure accurate dosing.

Place the ring on the required dose by turning anti-clockwise. Place the pre-filled oral syringe in the animal's mouth and expel the required dose on the back of the tongue in dogs or into the cheek pouch of horses.

10. WITHDRAWAL PERIOD(S)

Not authorised for use in horses intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf-life after first opening the immediate packaging: 56 days (8 weeks).
Do not use this veterinary medicinal product after the expiry date which is stated on the container after EXP.
The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species:
Dogs
None
Horses
Sedation lasts for approximately six hours, although the actual time and depth of sedation are very dependent on the status of the individual animal.
Increasing the dosage above that recommended results in prolonged action and side effects, but no greater sedation.

Special precautions for use in animals:
The veterinary medicinal product should be used with caution and with reduced dosage in the case of hepatic disease or in debilitated animals.
Acepromazine has negligible analgesic effects. Painful activities should be avoided when handling tranquillized animals, unless treated with appropriate analgesics.
After administration of this veterinary medicinal product, animals should be kept in a calm place and sensorial stimuli should be avoided as far as possible.

Dogs
Use of this veterinary medicinal product in dogs less than 17.5 kg bodyweight should be based on a careful benefit: risk assessment by the responsible veterinarian.
Owing to limitations of the dosing- device in delivering small doses use in small (less than 17,5 kg) dogs is not recommended for light sedation in sensitive individuals and breeds.
In dogs with the ABCB1-1Δ (also called MDR1) mutation, acepromazine tends to cause more profound and prolonged sedation. In these dogs the dose should be reduced by 25%-50%.

In some dogs, particularly Boxers and other short-nosed breeds, spontaneous fainting or syncope may occur, due to sinoatrial block caused by excessive vagal tone, and an attack may be precipitated by acepromazine, so a low dose should be used. Where there is a history of this type of syncope, or if it is suspected because of excessive sinus arrhythmia, it may be advantageous to control the dysrhythmia with atropine given just before the acepromazine.
Large breeds: it has been noted that large breeds of dogs are particularly sensitive to acepromazine and the minimum dose possible should be used in these breeds.
Acepromazine should be used cautiously as a restraining agent in aggressive dogs as it may make the animal more prone to startle and react to noises or other sensory inputs.

Horses
In stallions, the lowest dose range is indicated to minimise prolapse of the penis.
Use of this veterinary medicinal product in horses less than 100 kg bodyweight should be based on a careful benefit: risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Acepromazine may cause sedation. Care should be taken to avoid accidental ingestion. Replace cap immediately after use. While replacing the cap a “click” must be heard to ensure proper closure. Keep the broached oral syringe in the original carton and make sure that the carton is closed properly. Keep the package out of sight and reach of children at all times. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician but DO NOT DRIVE as sedation can occur.
Wash hands and exposed skin thoroughly after use.
People with sensitive skin or in continuous contact with this veterinary medicinal product are advised to wear impermeable gloves.
Avoid contact with eyes.
If accidental eye contact occurs, flush gently with running water for 15 minutes and seek medical advice if any irritation persists.

Pregnancy and lactation:
The safety of this veterinary medicinal product during pregnancy and lactation has not been studied in the target species; use only accordingly to the benefit-risk assessment by the responsible veterinarian.
Please see also Section on adverse reactions relating to disturbances in fertility in mares.

Interaction with other medicinal products and other forms of interaction:
Acepromazine potentiates the action of centrally depressant drugs.
Simultaneous administration, or administration to animals recently treated with organophosphates or procaine hydrochloride (a local anaesthetic) should be avoided, since these molecules enhance the toxic effects of acepromazine.
Since acepromazine decreases sympathetic nervous system tone, simultaneous treatment with blood pressure lowering products should not take place.
Antacids may cause a decrease in the gastrointestinal absorption of acepromazine after oral administration.
Opiates and adrenaline may enhance the hypotensive effects of acepromazine.

Overdose (symptoms, emergency procedures, antidotes):
Overdose results in an earlier onset of the sedative symptoms and in a prolonged effect. Toxic effects are ataxia, hypotension, hypothermia and central nervous system (extrapyramidal) effects. Noradrenaline, but not adrenaline, can be used to counteract the cardiovascular effects

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

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

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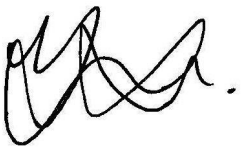
15. OTHER INFORMATION

White LLDPE (linear low-density polyethylene) pre-filled oral syringe of different sizes: 4 ml containing 3 gram, 8 ml containing 6 gram, 14 ml containing 10 gram and 14 ml containing 12 gram. The 3 and 6 gram syringes have a dosage ring, graduated every 0.25, 0.5 and 1 gram. The 10 and 12 gram syringes have a dosage ring graduated every 0.5 and 1 gram. The syringes are tightly closed with a LLDPE cap. Each pre-filled oral syringe is packed in a cardboard box.

Pack sizes:
Box with 1 pre-filled oral syringe of 3 gram, 6 gram, 10 gram or 12 gram.
Multi-pack with 12 boxes each containing 1 pre-filled oral syringe of 3 gram, 6 gram, 10 gram or 12 gram.

Not all pack sizes may be marketed.



Approved: 27 April 2022