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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. 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

4. TARGET SPECIES

Dogs and horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

Not authorised for use in horses intended for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within: 56 days (8 weeks).
Once opened use by: …….

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Acepromazine causes sedation and is DANGEROUS IF INGESTED. Replace push-fit cap immediately after use and return syringe to the original carton.
Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 41821/4044

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Container (pre-filled oral syringe)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquigel 35 mg/g oral gel

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:
Acepromazine (as acepromazine maleate) 35.0 mg/g

3. TARGET SPECIES

Dogs and horses

4. ROUTES OF ADMINISTRATION

Oral use
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Not authorised for use in horses intended for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within: 56 days (8 weeks).
Once opened use by: ……..

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Tranquigel 35 mg/g oral gel for dogs and horses

2. Composition

Each gram contains:

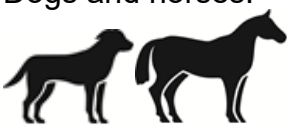
Active substances:
Acepromazine (as acepromazine maleate) 35.0 mg

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

Clear, viscous, orange-yellow gel.

3. Target species

Dogs and horses.



4. Indications for use

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. Special warnings

Special warnings:

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 safe use in the target species:
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 has not been established during pregnancy and lactation.
Use only according to the benefit-risk assessment by the responsible veterinarian.
Please see also Section *Adverse events* 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:
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.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypotension (low blood pressure)
Undetermined frequency (cannot be estimated from the available data)	Tachycardia (increased heart rate), arrhythmia (irregular heart beat) Increased respiratory rate Miosis (contraction of the pupil), ataxia (incoordination), central nervous system stimulation (generalised)[a] Lacrimation

	Aggression[a]

[a] Contradictory clinical signs

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hyperthermia/hypothermia[a]
Undetermined frequency (cannot be estimated from the available data)	Hypotension (low blood pressure)[b] Decreased red blood cell count[c], decreased haemoglobin[c], thrombocytopenia (decrease in platelets)[c], leucopenia (decrease in white blood cells)[c] Fertility disorder[d], penile prolapse[e], paraphimosis (foreskin does not return to the normal position)[f], priapism (persistent erection)[g] Aggression[h] Central nervous system stimulation (generalised)[h] Prolapse of the nictating membrane (third eyelid prolapse)[i]

[a] Inhibition of temperature regulation.
[b] Due to a decrease of the sympathetic nervous system tone. Transient.
[c] Transient and reversible.
[d] Due to increased prolactin secretion which may lead to disturbances in fertility.
[e] Due to 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.
[f] The foreskin does not return to the normal position. May occur in sequal to priapism.
[g] Persistent erection.
[h] Contradictory clinical signs.
[i] Third eyelid.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: national system details.

8. Dosage for each species, routes and method of administration

Oral use.

Dogs

Light sedation: 0.5 – 1.0 mg acepromazine / kg body weight (corresponding to 0.14 – 0.29 g of veterinary medicinal 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 veterinary medicinal product per 10 kg body weight)

Horses

Moderate sedation: 0.150 mg acepromazine / kg body weight (corresponding to 0.43 g of veterinary medicinal product per 100 kg body weight)

Deeper sedation: 0.225 mg acepromazine / kg body weight (corresponding to 0.64 g of veterinary medicinal 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 safe use in the target species.**

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 after 12 hours.
To ensure a correct dosage, body weight should be determined as accurately as possible.

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 periods

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. Do not use this veterinary medicinal product after the expiry date which is stated on the container and carton after Exp. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 56 days (8 weeks).

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 41821/4044

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

To be completed nationally.

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:
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

<Local representatives <and contact details to report suspected adverse reactions>:>

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

To be completed nationally.

Gavin Hall
Approved: 31 January 2025