LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PREFILLED SYRINGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquiline 35 mg/ml oral gel for dogs.
Acepromazine.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Acepromazine (as Acepromazine maleate)	35.00 mg

3. PHARMACEUTICAL FORM

Oral gel.

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening: 3 months.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not refrigerate or freeze.
Protect from light.
Keep the broached containers in the outer carton in order to protect from light. Store in a dry place.

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

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

Floris Holding BV
Kempenlandstraat 33 / 35
5262 GK Vught
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 56190/3002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

GLASS BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquiline 35 mg/ml oral gel for dogs.
Acepromazine.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Acepromazine (as Acepromazine maleate)	35.00 mg

3. PHARMACEUTICAL FORM

Oral gel.

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

This product must be used out of sight and reach of children.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening: 3 months.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not refrigerate or freeze.
Protect from light.
Keep the broached containers in the outer carton in order to protect from light. Store in a dry place.

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

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

Floris Holding BV
Kempenlandstraat 33 / 35
5262 GK Vught
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 56190/3002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON CONTAINING PREFILLED SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquiline 35 mg/ml oral gel for dogs.
Acepromazine.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Acepromazine (as Acepromazine maleate)	35.00 mg

3. PHARMACEUTICAL FORM

Oral gel.

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

User warnings

Acepromazine may cause sedation. Care should be taken to avoid accidental ingestion. To avoid accidental ingestion by a child when using the prefilled syringe, replace cap immediately after use. Keep the broached oral syringe in the original

carton and make sure that the carton is closed properly. This product must be used and kept out of sight and reach of children. In case of accidental ingestion, seek medical advice immediately, informing the health professionals of phenothiazine poisoning. Show the package leaflet or the label to the doctor. DO NOT DRIVE as sedation and changes in blood pressure may occur.

People with known hypersensitivity to acepromazine or other phenothiazines or to any of the excipients should avoid contact with the veterinary medicinal product. Persons with sensitive skin or in frequent contact with the product are advised to wear impermeable gloves. Wash hands and exposed skin thoroughly after use. In case of accidental spillage onto the skin, immediately after exposure wash the exposed skin with large amounts of water.

This product may cause mild eye irritation. 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.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening: 3 months.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not refrigerate or freeze.
Protect from light.
Keep the broached containers in the outer carton in order to protect from light. Store in a dry place

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.
To be supplied only on veterinary prescription.

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

Floris Holding BV
Kempenlandstraat 33 / 35
5262 GK Vught
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 56190/3002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON CONTAINING GLASS BOTTLE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquiline 35 mg/ml oral gel for dogs.
Acepromazine

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Acepromazine (as Acepromazine maleate)	35.00 mg

3. PHARMACEUTICAL FORM

Oral gel.

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

User warnings

Acepromazine may cause sedation. Care should be taken to avoid accidental ingestion. To avoid accidental ingestion by a child when using the glass bottle, do not leave the filled syringe unattended and store the properly closed bottle and used

syringe in the original carton. This product must be used and kept out of sight and reach of children. In case of accidental ingestion, seek medical advice immediately, informing the health professionals of phenothiazine poisoning. Show the package leaflet or the label to the doctor. DO NOT DRIVE as sedation and changes in blood pressure may occur.

People with known hypersensitivity to acepromazine or other phenothiazines or to any of the excipients should avoid contact with the veterinary medicinal product. Persons with sensitive skin or in frequent contact with the product are advised to wear impermeable gloves. Wash hands and exposed skin thoroughly after use. In case of accidental spillage onto the skin, immediately after exposure wash the exposed skin with large amounts of water.

This product may cause mild eye irritation. 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.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening: 90 days.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not refrigerate or freeze.
Protect from light.
Keep the broached containers in the outer carton in order to protect from light. Store in a dry place.

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.
To be supplied only on veterinary prescription.

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

Floris Holding BV
Kempenlandstraat 33 / 35
5262 GK Vught
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 56190/3002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Tranquiline 35 mg/ml oral gel for dogs

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

Marketing authorisation holder:
Floris Holding BV
Kempenlandstraat 33 / 35
5262 GK Vught
The Netherlands

Manufacturer responsible for batch release:
Floris Veterinaire Produkten BV
Kempenlandstraat 33
GK 5262 Vught
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquiline 35 mg/ml oral gel for dogs.
Acepromazine (as acepromazine maleate).

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

A clear yellow gel for oral administration.
Each ml of product contains:

Active substance

Acepromazine	35.00 mg
(as Acepromazine maleate)	(47.50 mg)

Excipients

Methyl parahydroxybenzoate (E218)	0.65 mg
Propyl parahydroxybenzoate	0.35 mg

4. INDICATIONS

For sedation and anaesthetic pre-medication.
Anti-emetic effect, in case of vomiting associated with motion sickness.

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 an existing tendency to convulsions or with epilepsy.

Do not use in dogs less than 3 months of age.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Hypotension, tachycardia, increase of respiratory rate, arrhythmia, miosis, lacrimation, ataxia and inhibition of temperature regulation.
Unwanted clinical signs of aggressiveness and generalised CNS stimulation may occur.
Inhibition of temperature regulation.

The following reversible changes are possible in the haemogram:
- transient decrease in erythrocyte count and haemoglobin concentration;
- transient decrease in thrombocyte and leukocyte counts.

Because it increases prolactin secretion, the administration of acepromazine may lead to disturbances in fertility.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

For oral use

Light sedation: 1.0 mg acepromazine / kg body weight
Deeper sedation: 2.0 mg acepromazine / kg body weight
Pre-medication: 3.0 mg acepromazine /kg body weight
Anti-emetic effect: 1.0 mg/kg body weight

The dose to be administered to dogs weighing ≥35 kg should not be more than 1 mg/kg for any level of sedation/premedication.

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, bodyweight, nervousness etc.) that may affect the sensitivity to sedatives.

The following tables are intended as a dispensing guide, depending on the desired degree of sedation:

Prefilled 10 ml syringe

	Light sedation		Deeper sedation		Pre-medication	
Bodyweight	**Gel (ml)**	**Dose range (mg/kg)**	**Gel (ml)**	**Dose range (mg/kg)**	**Gel (ml)**	**Dose range (mg/kg)**
> 17.5 kg – 25 kg	0.50	1.00 – 0.70	1.00	2.00 – 1.40	1.50	3.00 – 2.10
> 25 kg – < 35 kg	0.50	0.70 – 0.50	1.50	2.10 – 1.50	2.00	2.80 – 2.00

Glass bottle

	Light sedation		Deeper sedation		Pre-medication	
Bodyweight	**Gel (ml)**	**Dose range (mg/kg)**	**Gel (ml)**	**Dose range (mg/kg)**	**Gel (ml)**	**Dose range (mg/kg)**
> 1.75 kg – 3.5 kg	0.05	1.00 – 0.50	0.10	2.00 – 1.00	0.15	3.00 – 1.50
> 3.5 kg – 5.25 kg	0.10	1.00 – 0.67	0.20	2.00 – 1.33	0.30	3.00 – 2.00
> 5.25 kg – 7.0 kg	0.15	1.00 – 0.75	0.30	2.00 – 1.50	0.45	3.00 – 2.25
> 7.0 kg – 8.75 kg	0.20	1.00 – 0.80	0.40	2.00 – 1.60	0.60	3.00 – 2.40
> 8.75 kg – 10.5 kg	0.25	1.00 – 0.83	0.50	2.00 – 1.67	0.75	3.00 – 2.50
> 10.5 kg – 14 kg	0.30	1.00 – 0.75	0.60	2.00 – 1.50	0.90	3.00 – 2.25
> 14 kg – 17.5 kg	0.40	1.00 – 0.80	0.80	2.00 – 1.60	1.20	3.00 – 2.40
> 17.5 kg – 21 kg	0.50	1.00 – 0.83	1.00	2.00 – 1.67	1.50	3.00 – 2.50
> 21 kg – 24.5 kg	0.60	1.00 – 0.86	1.20	2.00 – 1.71	1.80	3.00 – 2.57
> 24.5 kg – 28 kg	0.70	1.00 – 0.88	1.40	2.00 – 1.75	2.10	3.00 – 2.63
> 28 kg – < 35 kg	0.80	1.00 – 0.80	1.60	2.00 – 1.60	2.40	3.00 – 2.40

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing. To ensure accuracy of dosing, the bodyweight of the animal to be treated should be determined prior to dosing.

Prefilled syringe
The product is filled into a 10 ml polyethylene syringe. The flanged plunger has a locking ring which should be adjusted to supply the volume required in accordance with the dosage guidelines. 1.0 ml intervals are printed on the syringe plunger, but the plunger is indented/flanged at intervals of 0.5 ml. A single turn of the locking ring will move the ring backwards allowing a dose volume of 0.5 ml to be expelled. Two turns of the locking ring will supply a dose volume of 1.0 ml. Three turns of the locking ring are required for a dose of 1.5 ml. The syringe is brought into the animal's mouth and the appropriate dose is expelled into the animal's cheek.
The gel can also be mixed with food.

Glass bottle
The product is filled into 10 ml glass bottles with child resistant closure and supplied with a syringe with a dose graduation allowing accurate dosing. The 1 ml syringe can administer 0.05 to 1.0 ml with 0.05 ml increments. Withdraw the appropriate dose from the bottle using the supplied syringe. The syringe is brought into the animal's mouth and the appropriate dose is expelled into the animal's cheek.
Some product will remain in the glass bottle, i.e. is not extractable.
The gel can also be mixed with food.

In dogs sedation usually sets in after 15-30 minutes and lasts 6-7 hours.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.
Do not refrigerate or freeze.
Protect from light.

Prefilled syringe:
After use, replace cap on syringe. Keep the broached containers in the outer carton in order to protect from light. Store in a dry place.

Glass bottle:
After use, replace child resistant closure on bottle.
Do not leave an oral dosing syringe containing product in the sight or reach of children
Keep the broached containers in the outer carton in order to protect from light. Store in a dry place.

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

Shelf-life after first opening the container: 3 months.

12. SPECIAL WARNINGS

Special precautions for use in animals:

The product is presented in a 10 ml prefilled syringe and 10 ml glass bottle with dosing syringe. The accuracy of dosing differs between the two presentations.

Prefilled syringe
Given the limitations of the prefilled syringe in delivering dose volumes of less than 0.5 mL, its use in animals weighing less than 17.5 kg bodyweight for sedation or in sensitive individuals and breeds is not recommended and the glass bottle with the 1 mL syringe should be used instead.
Use of this veterinary medicinal product (prefilled syringe) in dogs less than 17.5 kg bodyweight should be based on a careful benefit:risk assessment by the responsible veterinarian.

Glass bottle
Use of the veterinary medicinal product with the 1ml dosing syringe in dogs less than 1.75 kg bodyweight should be based on a careful benefit:risk assessment by the responsible veterinarian (see section 4.9).

This 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.
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.

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. To avoid accidental ingestion by a child when using the prefilled syringe,

replace cap immediately after use. Keep the broached oral syringe in the original carton and make sure that the carton is closed properly. To avoid accidental ingestion by a child when using the glass bottle, do not leave the filled syringe unattended and store the properly closed bottle and used syringe in the original carton. This product must be used and kept out of sight and reach of children. In case of accidental ingestion, seek medical advice immediately, informing the health professionals of phenothiazine poisoning. Show the package leaflet or the label to the doctor. DO NOT DRIVE as sedation and changes in blood pressure may occur.

People with known hypersensitivity to acepromazine or other phenothiazines or to any of the excipients should avoid contact with the veterinary medicinal product. Persons with sensitive skin or in frequent contact with the product are advised to wear impermeable gloves. Wash hands and exposed skin thoroughly after use. In case of accidental spillage onto the skin, immediately after exposure wash the exposed skin with large amounts of water.

This product may cause mild eye irritation. 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:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. The use of acepromazine during pregnancy is not recommended. Use only according to the benefit/risk assessment by the responsible veterinarian.
Please see also Section 6 concerning fertility in bitches.

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):

Overdosage results in an earlier onset of the sedative symptoms and in a prolonged effect.
Toxic effects are ataxia, hypotension, hypothermia and extrapyramidal effects.
Antidote: Noradrenaline can be used to counteract the cardiovascular effects, but not adrenaline.

Incompatibilities:

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, 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

February 2022

15. OTHER INFORMATION

For animal treatment only

Acepromazine is a phenothiazine derivative. This group of molecules belongs to the neuroleptics: they depress the central nervous system and exert associated effects on the autonomic system. These effects are due to their interference with different neurotransmitter receptors (dopaminergic, adrenergic) and to their interference with hypothalamic performance. The sedative activity starts within 15 to 30 minutes of treatment and lasts for 6 -7 hours.
Acepromazine is partly absorbed from the gastrointestinal tract. Plasma protein binding is high and it is extensively distributed throughout the body tissues. Plasma levels are usually low. Acepromazine is highly metabolised, with the urine as the main route of excretion.

Veterinary prescription only.

Package quantities

Prefilled syringes

Container:	White, high-density polyethylene syringe barrel. White, low-density polyethylene syringe plunger.
Closure:	White, high-density polyethylene, push-fit cap.
Fill volume:	10 ml
Dosing device:	The product is presented in an oral dosing syringe which is graduated at 1ml intervals.

Glass bottles

Container:	Amber Type III glass bottles of 10 ml volume.

Closure:	High-density polyethylene/low-density polyethylene child resistant closures
Extractable volume:	9.8 ml of Tranquiline gel can be withdrawn from each 10 ml amber glass bottle
Dosing device:	1.0 ml polypropylene oral dosing syringe, graduated at 0.05 ml intervals, is supplied with the 10 ml amber glass bottle.

Not all pack sizes may be marketed.

Approved 23 February 2022