Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tranquiline 35 mg/ml Oral Gel for Dogs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance	
Acepromazine	35.00 mg
(as Acepromazine maleate)	(47.50 mg)
Excipients	
Preservatives	
Methyl parahydroxybenzoate (E218)	0.65 mg
Propyl parahydroxybenzoate (E216)	0.35 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral gel.
Clear yellow gel.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

For sedation and anaesthetic pre-medication.
Neuroleptanalgesia in combination with a morphine derivative.
Anti-emetic effect, symptomatic therapy in case of vomiting and motion sickness.

4.3 Contraindications

Do not use in dogs weighing less than 17.5 kg body weight.
Do not use in animals in shock, in severe emotional excitation, with an existing tendency to convulsion or during *Status epilepticus.*
Do not use in case of hypersensitivity to the active substance or any of the excipients.

4.4 Special warnings for each target species

Acepromazine can precipitate fainting in brachycephalic dogs. Large breeds of dog are particularly sensitive to acepromazine and the minimum dose possible should be used in these breeds.

4.5 Special precautions for use

Special precautions for use in animals

Acepromazine has little, if any, analgesic effect, so painful procedures must be avoided.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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 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.
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.

4.6 Adverse reactions (frequency and seriousness)

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:
- 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.

4.7 Use during pregnancy, lactation or lay

Teratological effects after the use of acepromazine in bitches have, to date, not been reported. However, as no specific study on teratological effects exists, the use of acepromazine during pregnancy is not recommended and should only take place following a suitable benefit/risk assessment by the responsible veterinary surgeon.

4.8 Interaction with other medicinal products and other forms of interaction

Acepromazine potentiates the action of centrally depressant drugs.
The simultaneous use of organic phosphate esters increases the toxicity of acepromazine.
Since acepromazine decreases sympathetic nervous system tone, the product should not be given at the same time as blood pressure reducing drugs.

4.9 Amounts to be administered and administration route

For oral administration

Dosage guidelines

1 ml gel contains 35 mg acepromazine – the dosage recommendation **per 17.5 kg bodyweight** is as follows, depending on the desired degree of sedation:

Indication	Dose	Dose volume	Dog weight
Slight sedation	1.0 mg/kg	0.5 ml	17.5 kg
Sedation	2.0 mg/kg	1.0 ml	17.5 kg
Pre-medication	3.0 mg/kg	1.5 ml	17.5 kg

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 palatable gel can also be mixed with food.

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

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.
Possible antidote to apnoea and syncope which may occur - methylamphetamine and soluble steroid.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Therapeutic group: Nervous System

ATC vet code: QN05AA04

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate
Sodium acetate trihydrate
Sodium cyclamate (E952)
Hydroxyethylcellulose
Glycerol (E422)
Purified water

6.2 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: 2 years

Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate or freeze.
Protect from light.
Keep the broached syringe in the original carton and store in a dry place.

6.5 Nature and composition of immediate packaging

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 1 ml intervals.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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.

7 MARKETING AUTHORISATION HOLDER

Floris Veterinaire Produkten BV
Kempenlandstraat 33
5262 GK Vught
The Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10492/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd March 2012
Date of last renewal: 13th January 2017

10 DATE OF REVISION OF THE TEXT

January 2017