1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Relaquine 35 mg/ml Oral Gel for Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Acepromazine	35.00 mg
(as Acepromazine maleate	47.50 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	0.65 mg
Propyl parahydroxybenzoate	0.35 mg
Sodium acetate trihydrate	
Sodium cyclamate (E952)	
Hydroxyethylcellulose	
Glycerol (E422)	
Purified water	

A clear yellow viscous liquid.

3. CLINICAL INFORMATION

3.1 Target species

Horses (non-food producing).

3.2 Indications for use for each target species

For sedation of horses.

3.3 Contraindications

Do not use in cases of post-traumatic shock or hypovolaemia.
Do not use in animals in a state of severe emotional excitation.
Do not use in animals with epilepsy.
Do not use in pregnant or lactating mares.
Do not use in animals with heart failure.
Do not use in animals with haematological disorders/coagulopathies.
Do not use in animals suffering from hypothermia.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in neonates.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In stallions, the lowest dose range is indicated to minimise prolapse of the penis.
The veterinary medicinal product should be used with caution and with reduced dosage in the case of cardiac or hepatic disease or in debilitated, hypovolemic or anaemic animals.
Acepromazine has negligible analgesic effects. Painful activities should be avoided when handling tranquillized animals.
Tranquillized horses should be kept in a calm place and sensorial stimuli should be avoided as far as possible.

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

This veterinary medicinal product may cause sedation. Avoid accidental ingestion. To avoid accidental ingestion by a child when using the prefilled syringe, replace the cap immediately after use and keep the syringe in the original carton. When using the glass bottle, do not leave the filled syringe and bottle unattended and store the properly closed bottle and used syringe in the original carton. Also beware that children do not have access to the feed when the veterinary medicinal product is mixed with feed. 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.

This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to acepromazine or to any of the excipients should avoid contact with the veterinary medicinal product. People with sensitive skin or in continuous contact with the veterinary medicinal product are advised to wear impermeable gloves.

This veterinary medicinal product may cause eye irritation. Avoid eye contact. In case of accidental eye contact, rinse the eye for 15 minutes with clean water and if irritation persists, seek medical advice and show the package leaflet or the label to the physician.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horse:

Rare (1 to 10 animals / 10,000 animals treated):	Excitation[1]
Very rare	Low blood pressure[2],

(<1 animal / 10,000 animals treated, including isolated reports):	Hypothermia[3], Hyperthermia[3] Decreased red blood cell count[4], Decreased haemoglobin[4], Low platelet count[4], Leucopenia[4] Infertility[5], Penile prolapse[6], Paraphimosis[7], Priapism[7] Aggression[8], Generalized central nervous system stimulation[8] Prolapse of the nictitating membrane

[1] Paradoxical reaction
[2] Since acepromazine decreases sympathetic nervous system tone, a transient drop in blood pressure may occur after administration.
[3] Inhibition of temperature regulation.
[4] Transient.
[5] Because it increases prolactin secretion, the administration of acepromazine may lead to disturbances in fertility.
[6] Due to the relaxation of the retractor penis muscles. Retraction of the penis should 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.
[7] Acepromazine has caused paraphimosis sometimes in sequel to priapism.
[8] Contradictory clinical signs

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Acepromazine should not be used in pregnant or lactating mares.
Acepromazine has the potential to induce hypotension in newborns when administered as a premedication for caesarean section in the mare.
Please see also Section 3.6 relating to disturbances in fertility.

3.8 Interaction with other medicinal products and other forms of interaction

Acepromazine potentiates the action of centrally depressant drugs.

Simultaneous administration, or administration to horses recently treated with organophosphates 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 may enhance the hypotensive effects of acepromazine.

3.9 Administration routes and dosage

For oral administration.

Prefilled syringe
The veterinary medicinal product is contained within a 10 ml or 15 ml polyethylene syringe. The plunger has a locking ring which should be adjusted to provide the volume required in accordance with the dosage guidelines. 1.0 ml intervals are printed on the syringe plunger, but it is also possible to dose at 0.5 ml intervals.

Before first use of the syringe, turn the locking ring clockwise until aligned with the 0.0 ml mark (side of the ring facing the barrel). Turn the locking ring anti-clockwise will move the ring backwards. Turn the locking ring backwards until the left side of the locking ring lines up with the volume of the oral gel to be administered.

Place the syringe in the animal's mouth and expel the required dose into the cheek pouch. The gel may also be mixed with food.

Glass bottle
The veterinary medicinal product is filled into 10, 15, 20, 30 and 50 ml glass bottles with CRC closure and supplied with a 5 ml syringe with a dose graduation allowing accurate dosing of 0.1 or 0.2 ml. 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.
The gel may also be mixed with food.

Amount(s) to be administered

Moderate sedation:0.15 mg acepromazine per kg bodyweight

Dosage guidelines:

Bodyweight (kg)	200	300	400	450	500	600
Dose (ml)	1.0	1.5	1.5	2.0	2.5	2.5

The above dosage information is provided as a guideline. The dose may be varied to administer between 0.5 and 1.5 times the above recommendation depending on the level of sedation required, i.e. for mild sedation, administer half the recommended dose and for deeper sedation, administer 1½ times the recommended dose.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Overdosage 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.**

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Not authorised for use in horses intended for human consumption.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QN05AA04.

4.2 Pharmacodynamics

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.

The desired effects observed after treatment with acepromazine include a general tranquillizing effect, anti-emetic effect and a slight anti-histaminic effect. There is no analgesic action. The neuroleptic effects are variable between individual animals.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 90 days.

5.3 Special precautions for storage

Do not store above 25 °C.
Protect from frost.
Protect from light.
After use, replace cap on syringe. Keep the broached syringe in the original carton and store in a dry place.

5.4 Nature and composition of immediate packaging

Prefilled syringe with white, high-density polyethylene prefilled syringe barrel and white, low-density polyethylene syringe plunger closed with a white, high-density polyethylene, push-fit cap. The prefilled syringe is graduated at 1 ml intervals.

Prefilled syringe with linear low-density polyethylene syringe closed with a linear low-density polyethylene, push-fit cap. The prefilled syringe is graduated at 1 ml intervals.

Amber glass vials type III, fitted with syringe adaptors and HDPE/LDPE CRC closures. The oral syringe of 5 ml is graduated at 0.1 or 0.2 ml intervals.

Pack sizes:
- Carton box including prefilled syringe of 10 ml.
- Carton box including prefilled syringe of 15 ml.
- Carton box including glass vials containing 9 ml, 14 ml, 18 ml, 28 ml and 48 ml product.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Floris Holding BV

7. MARKETING AUTHORISATION NUMBER(S)

VPA22969/004/001

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).