LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

SYRINGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Relaquine 35 mg/ml Oral Gel for Horses

Acepromazine

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 35 mg acepromazine (as acepromazine maleate 47.50 mg)

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

10 ml syringe
15 ml syringe

5. TARGET SPECIES

Horses

6. INDICATIONS

For sedation of horses

7. METHOD AND ROUTE OF ADMINISTRATION

For oral administration.

Moderate sedation of horses: 0.15 mg acepromazine per kg bodyweight

The dose may be varied to administer between 0.5 and 1.5 times the above recommendation according to the level of sedation required, i.e. for mild sedation, administer half the recommended dose and for deeper sedation, administer 1.5 times the recommended dose.

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.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not authorised for use in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

User warning
Wash hands and exposed skin thoroughly after use.
Persons with sensitive skin or in continuous contact with the 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.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or product label to the physician, but DO NOT DRIVE as sedation can occur.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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 56190/3001

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOTTLE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Relaquine 35 mg/ml Oral Gel for Horses

Acepromazine

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 35 mg acepromazine (as acepromazine maleate 47.50 mg)

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

9 ml bottle
14 ml bottle
18 ml bottle
28 ml bottle
48 ml bottle

5. TARGET SPECIES

Horses

6. INDICATIONS

For sedation of horses

7. METHOD AND ROUTE OF ADMINISTRATION

For oral administration.

Moderate sedation of horses: 0.15 mg acepromazine per kg bodyweight

The dose may be varied to administer between 0.5 and 1.5 times the above recommendation according to the level of sedation required, i.e. for mild sedation, administer half the recommended dose and for deeper sedation, administer 1.5 times the recommended dose.

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.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not authorised for use in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

User warning
Wash hands and exposed skin thoroughly after use.
Persons with sensitive skin or in continuous contact with the 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.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or product label to the physician, but DO NOT DRIVE as sedation can occur.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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 56190/3001

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SYRINGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Relaquine 35 mg/ml Oral Gel for Horses

Acepromazine

2. QUANTITY OF THE ACTIVE SUBSTANCE

35 mg/ml

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

10 ml
15 ml

4. ROUTE OF ADMINISTRATION

For oral administration

5. WITHDRAWAL PERIOD(S)

Not authorised for use in horses intended for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the syringe: 90 days
Once broached (opened) use by ……

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Relaquine 35 mg/ml Oral Gel for Horses

Acepromazine

2. QUANTITY OF THE ACTIVE SUBSTANCE

35 mg/ml

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

9 ml
14 ml
18 ml
28 ml
48 ml

4. ROUTE OF ADMINISTRATION

For oral administration

5. WITHDRAWAL PERIOD(S)

Not authorised for use in horses intended for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the syringe: 90 days
Once broached (opened) use by ……

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Relaquine 35 mg/ml Oral Gel for 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
Floris Holding BV
Kempenlandstraat 33 / 35
5262 GK Vught
The Netherlands

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Relaquine 35 mg/ml Oral Gel for Horses

Acepromazine

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

Clear yellow gel for oral administration.
Each ml contains 35 mg acepromazine (as acepromazine maleate 47.50 mg) as active substance, 0.65 mg methyl parahydroxybenzoate (E218) and 0.35 mg propyl parahydroxybenzoate as preservatives.

4. INDICATIONS

For sedation of horses.

5. 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 the case of known hypersensitivity to the active substance or any of the excipients of the product.
Do not use in neonates.

6. ADVERSE REACTIONS

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.
Penile prolapse may occur 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. Acepromazine has caused paraphimosis sometimes in sequel to priaprism.
In rare cases, (more than 1 but less than 10 animals in 10,000 animals), paradoxical excitation reactions can develop.
Contradictory clinical signs of aggressiveness and generalised CNS stimulation may occur.
Prolapse of the nictitating membrane has also been cited as a possible adverse effect in horses.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

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

Horses.

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

Moderate sedation of horses: 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 according to the level of sedation required, i.e. for mild sedation, administer half the recommended dose and for deeper sedation, administer 1.5 times the recommended dose.

9. ADVICE ON CORRECT ADMINISTRATION

For oral administration.

Prefilled syringe
The 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 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 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.

10. WITHDRAWAL PERIOD

Not authorised for use in horses intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.
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.
Do not use this veterinary medicinal product after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

Shelf life after first opening the syringe: 90 days
When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
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.
In stallions the lowest dose range is indicated to minimise prolapse of the penis.
The 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.

User warnings:
Wash hands and exposed skin thoroughly after use.

Persons with sensitive skin or in continuous contact with the 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.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or product label to the physician, but DO NOT DRIVE as sedation can occur.

Pregnancy and lactation:
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 6 relating to disturbances in fertility.

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 effect 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 central nervous system (extrapyramidal) effects.
Noradrenaline, but not adrenaline, can be used to counteract the cardiovascular effects.

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.

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

Package quantities
Polyethylene adjustable syringe containing 10 ml or 15 ml gel.
Amber Type III glass bottles containing 9, 14, 18, 28 and 48 ml gel.

Not all pack sizes may be marketed.

Legal category
To be supplied only on veterinary prescription.

Marketing Authorisation number: Vm 56190/3001

Approved 23 February 2022