Relaquine

Oral sedative gel

Relaquine contains Acepromazine (ACP) 35 mg/ml in an oral gel and has a general tranquillizing effect in horses.

What can it be used for?

For situations where sedation is required to enable a procedure to be carried out easily and safely, for example interventions such as shoeing, clipping, travelling and dentistry.

The opened shelf life of this product is 28 days.

Oral administration

Can be administered orally by placing the syringe in the animal's mouth and expelling the required dose into the cheek pouch. Alternatively the gel may also be mixed with food.

Easy dosing mechanism

Available in a 10 ml plastic multi-dose syringe with an easy ring dial dosing mechanism.

Amount(s) to be administered

Moderate sedation:
0.15 mg acepromazine per kg body weight.

Dosage guidelines

Body weight (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 1.5 times the recommended dose.

Legal category

POM-V

Dechra
Veterinary Products

Summary of product characteristics

1. Name of the veterinary medicinal product
Relaquine 35mg/ml Oral Gel for Horses

2. Qualitative and quantitative composition
Active substance
Acepromazine - 35.00 mg/ml
(as Acepromazine maleate) - (47.50 mg/ml)
Excipients: Preservatives
Methyl parahydroxybenzoate - 0.65 mg/ml
Propyl parahydroxybenzoate - 0.35 mg/ml
For the full list of excipients, see Section 6.1.

3. Pharmaceutical form
Oral gel. Clear yellow gel for oral administration.

4. Clinical particulars
4.1. Target species - Horse.
4.2. Indications for use, specifying the target species - For sedation of horses.
4.3. Contraindications
Do not use in animals in post-traumatic shock.
Do not use in animals with existing severe emotional excitation.
Do not use in animals with epilepsy.
Do not use in pregnant or lactating mares.
4.4. Special warnings for each target species
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 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.
4.5. Special precautions for use
i) Special precautions for use in animals
Do not use in cases of post-traumatic hypovolaemia.
ii) Special precautions to be taken by the person administering the medicinal product to animals
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, contact a doctor showing the package leaflet or product label to the doctor.
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.
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.
4.7. Use during pregnancy, lactation or lay
Acepromazine should not be used in pregnant or lactating mares.
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, it should not be given at the same time as blood pressure reducing drugs.
4.9. Amount(s) to be administered and administration route
Administration route
For oral administration. 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. Amount(s) to be administered
Moderate sedation: 0.15 mg acepromazine per kg body weight

Dosage guidelines						
Body weight (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 10 times the recommended dose. Because of the difficulty in ensuring the accurate delivery of small doses, the product should only be used in horses of less than 200 kg body weight in accordance with a benefit/risk assessment by the responsible veterinarian.

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 central nervous system (extrapyramidal) effects. Noradrenaline can be used to counteract the cardiovascular effects. Methylamphetamine has been recommended for the treatment of aberrant reactions in horses.
4.11. Withdrawal period(s)
Not to be used in animals intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

5. Pharmacological 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. The desired effects observed after treatment with acepromazine include a general tranquillizing effect, anti-emetic effect and a slight antihistaminic effect. There is no analgesic action. The neuroleptic effects are variable between individual animals.
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 (E216)
Sodium acetate trihydrate
Sodium cyclamate (E952)
Hydroxyethylcellulose
Glycerol (E422)
Purified water
6.2. Incompatibilities
Simultaneous administration, or administration to horses recently treated with organophosphates should be avoided, since these molecules enhance the toxic effects of acepromazine. Simultaneous treatment with blood pressure lowering products should be avoided.
6.3. Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years Shelf-life after first opening the container: 28 days
6.4. Special precautions for storage
Do not store above 25°C.
Protect from frost.
Protect from light.
When the container is broached (opened) for the first time, use within 28 days. After use, replace cap on syringe. Keep the broached syringe in the original carton and store in a dry place.
6.5. Nature and contents 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 product or waste materials derived from the use of such products.
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 B.V.
Kempenlandstraat 33
5262 GK Vught, The Netherlands

8. Marketing authorisation number
Vm 36057/4001

9. Date of first authorisation
10 March 2011

10. Date of revision of the text
March 2011

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