

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedalin 35 mg/ml oral gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Acepromazine 35.0 mg
(as acepromazine maleate 47.5 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-4-hydroxybenzoate	0.65 mg
Propyl-4-hydroxybenzoate	0.35 mg
Sodium acetate trihydrate	
Sodium cyclamate	
Hydroxyethyl cellulose	
Glycerol 85% Solution	
Water purified	

Homogenous yellow-orange transparent gel.

3. CLINICAL INFORMATION

3.1 Target species

Horse.

3.2 Indications for use for each target species

For sedation of horses.

3.3 Contraindications

Do not use in animals in shock or post traumatically, or with existing severe emotional excitation or epilepsy.

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 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:

Do not use in cases of post traumatic hypovolemia.

Penile collapse 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 for breeding stallions. Acepromazine has caused paraphimosis sometimes in a sequel to priapism.

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

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands and exposed skin thoroughly after use. Persons with sensitive skin or in continuous contact 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horse:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypotension ^{1,6} Hypothermia ² Thrombocytopenia ^{1,3} , leucopenia ^{1,3} , decreased hemoglobin ^{1,3} Fertility disorders ⁴ Penile prolapse ⁵ , paraphimosis, priapism
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¹ Transient

² Inhibition of temperature regulation

³ Reversible

⁴ Following increased prolactin secretion due to acepromazine

⁵ 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.

⁶ Acepromazine decreases sympathetic nervous system tone.

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

Pregnancy and lactation:

Do not use in pregnant or lactating mares.

In stallions the lowest dose range is indicated to minimise prolapse of the penis.

3.8 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.

3.9 Administration routes and dosage

Oral use.

Moderate sedation: 0.15 mg acepromazine/kg bodyweight.

The dose may be varied to administer between $\frac{1}{2}$ and $1 \frac{1}{2}$ 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 $1 \frac{1}{2}$ times the recommended dose.

Because of the difficulties in ensuring the accurate delivery of small doses, the product should only be used in horses of less than 200 kg bodyweight in accordance with the benefit-risk assessment by the responsible veterinarian.

The syringe is brought into the animal's mouth and the suitable dose is pumped into the cheek pouch. The palatable gel can also be mixed with food.

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 but not with deeper sedation.

Toxic effects are: ataxia, hypotensia, hypothermia, extrapyramidal effects.

Noradrenaline can be used to counteract the cardiovascular effects.

Methylamphetamine has been recommended for the treatment of aberrant reactions in horses.

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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN05AA04.

4.2 Pharmacodynamics

Acepromazine is a phenothiazine derivate. 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 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 neuroleptical effects are variable between individual animals. Acepromazine is partly absorbed from the gastrointestinal tract. It binds extremely well to plasma proteins and is extensively distributed over the body tissues. Plasma levels are usually low. Acepromazine is highly metabolized and excreted in urine. The sedative activity starts within 15-30 minutes and lasts up to 6-7 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Simultaneous administration or administration to patients who were treated recently with organophosphates should be avoided, since these molecules enhance the toxic effects of acepromazine.

Simultaneous treatment with blood pressure lowering products should be avoided.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

10 ml white, medium density polyethylene pre-filled oral dial-a-dose syringe and syringe plunger with white low density polyethylene cap (push fit).

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.

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

Vetoquinol UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 08007/5020

8. DATE OF FIRST AUTHORISATION

25 March 1996.

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

August 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 01 September 2026