1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedalin 35 mg/ml oral gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Acepromazine 35.00 mg
(as acepromazine maleate)

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	0.65 mg
Propyl parahydroxybenzoate	0.35 mg
Sodium acetate	
Sodium cyclamate	
Hydroxyethylcellulose (4500-6000)	
Glycerol (85 per cent)	
Purified water	

Yellow-orange transparent gel.

3. CLINICAL INFORMATION

3.1 Target species

Horses (non-food producing).
Dogs.

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

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

Acepromazine can precipitate fainting in brachycephalic dogs. Large breeds of dogs are particularly sensitive to acepromazine and the minimum dose possible should be used in these breeds.
Duration of action may be prolonged. This may affect performance and acepromazine may appear in drug tests for some time. Acepromazine is classified as a prohibited substance (controlled medication) in equine sport.

3.5 Special precautions for use

Special precautions for safe use in the target species:
During sedation, horses will maintain normal visual and auditory acuity so that loud noises and rapid movement may cause arousal from the sedated state. It is therefore important to keep treated horses in a quiet environment and avoid sensory stimulation as far as possible.

Horses should not normally be ridden within 36 hours of administration of a clinical dose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs, horses:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypotension[1,2] Hypothermia[3], Hyperthermia[,3], Thrombocytopenia[1,4], leucopenia[1,4], decreased red blood cell count, decreased hemoglobin[1,4], Fertility disorders[5], Penile prolapse[6], priapism, paraphimosis[7]

[1] Transient.
[2] Since acepromazine decreases sympathetic nervous system tone.
[3] Inhibition of temperature regulation.
[4] Reversible.
[5] Following increased prolactin secretion due to acepromazine.
[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] Sometime occurs in a sequel to priapism.

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 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:
Teratological effects after the use of acepromazine in mares or bitches have to date not been reported. However, as no specific study on teratological effects exist, it is recommended that acepromazine should be used only with caution in the first trimester of pregnancy.

Otherwise, this veterinary medicinal product can be used in pregnant animals.

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.

The veterinary medicinal product doser (10 ml) contains 10 oral doses (1 ml each).

Horses:
Slight sedation: 0.1 - 0.2 mg/kg; 2 - 3 oral doses per 500 kg b/w.
Sedation: 0.3 - 0.4 mg/kg; 4 - 6 oral doses per 500 kg b/w.
Premedication: 0.3 - 0.4 mg/kg; 4 - 6 oral doses per 500 kg b/w.

Dogs:
Slight sedation: 1.0 mg/kg; 0.5 oral doses per 17.5 kg b/w.
Sedation: 2.0 mg/kg; 1.0 oral dose per 17.5 kg b/w.
Premedication: 3.0 mg/kg; 1.5 oral doses per 17.5 kg b/w.

The veterinary medicinal product is packed in a 10 ml polyethylene syringe which allows easy administration. The syringe is brought into the animal's mouth and the suitable doses are pumped against the animal's cheek. The palatable veterinary medicinal product can also be mixed with food.

Do not use the same syringe to treat more than one animal, unless horses are running together or in direct contact with each other on the same premises.

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, extrapyramidal effects.
Antidote: Noradrenaline can be used to counteract the cardiovascular effects.
Methylamphetamine has been recommended for the treatment of aberrant reactions in horses. Possible antidote to apnoea and syncope which may occur in dogs - Methylamphetamine and soluble steroid.

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

Dogs:
Not applicable.

Horses:
Treated horses may never be slaughtered 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.

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 metabolised 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

None known.

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

Graduated 10 ml white linear medium density polyethylene oral doser syringe with a linear medium density polyethylene plunger and closed with a low-density polyethylene cap.
Content: 10 ml homogenous yellow-orange aqueous gel.

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

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10521/034/001

8. DATE OF FIRST AUTHORISATION

01/10/2000

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

04/09/2026

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).