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 substance
Acepromazine 35.0mg (as Acepromazine Maleate 47.5mg)
List of Excipients
Methyl-4-hydroxybenzoate 0.65 mg and Propyl-4-hydroxybenzoate 0.35 mg, as preservatives

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral gel
Yellow-orange transparent 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 Contra-indications

Not for use in animals in shock or post traumatically, or with existing severe emotional excitation or epilepsy

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.

4.5 Special precautions for use

i) Special precautions for use in animals

Do not use in cases of post traumatic hypovolemia

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

In case of accidental ingestion contact a physician showing the pack insert or product 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.

4.6 Adverse reactions (frequency and seriousness)

Since acepromazine decreases sympathetic nervous system tone, a transient drop in blood pressure may occur after its administration.

Inhibition of temperature regulation.

The following reversible changes are possible in the haemogram:

Transient decrease in the erythrocyte count and haemoglobin concentration as well as in thrombocyte and leukocyte counts.

Because it increases prolactin secretion, the administration of acepromazine may lead to disturbances in fertility.

Penile prolapsed 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 a sequel to priapism.

4.7 Use during pregnancy, lactation or lay

Acepromazine should not be used in pregnant or lactating mares.

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

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 Amounts to be administered and administration route

Moderate sedation: 0.15 mg acepromazine/kg bodyweight.

The dose may be varied to administer between ½ and 1 ½ 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 ½ 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 200kg bodyweight in accordance with a 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.

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, 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.

4.11 Withdrawal period

Not authorised for use in horses intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Acepromazine is a phenothiazine derivate. This group of molecules belongs to the neuroleptica: 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.

ATC Vet Code: QN05AA04

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl-4-hydroxybenzoate
Propyl-4-hydroxybenzoate
Sodium Acetate Trihydrate
Sodium Cyclamate
Hyetellose
Glycerol 85% Solution
Water Purified

6.2 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.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 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)

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 of waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

8. MARKETING AUTHORISATION NUMBER

Vm 08007/5020

9. DATE OF FIRST AUTHORISATION

25 March 1996

10. DATE OF REVISION OF THE TEXT

July 2025

Gavin Hall
Approved: 25 July 2025