Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedalin Oral Gel 3.5 %w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance
Acepromazine (as Acepromazine Maleate) 3.5 % w/v

Excipients
Methyl Parahydroxybenzoate 0.065 % w/v
Propyl Parahydroxybenzoate 0.035 % w/v

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral gel.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses declared as not being intended for human consumption.
Dogs.

4.2 Indications for use, specifying the 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.

4.3 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 case of hypersensitivity to the active substance.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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

None.

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 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 a sequel to priapism.

4.7 Use during pregnancy, lactation or lay

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 product can be used in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interactions

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

For oral administration.
Sedalin Gel oral doser (10 ml) contains 10 oral doses (1 ml each).

Horse:
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

Dog:
slight sedation: 1.0 mg/kg 0.5 oral dose 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 dose per 17.5 kg b/w

Sedalin Gel 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 Sedalin Gel can also be mixed with food.

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

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, 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.

4.11 Withdrawal period(s)

Dog:
Not applicable.

Horse:
Treated horses may never be slaughtered for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Nervous system, psycholeptics, antipsychotics, phenothiazines with aliphatic side-chain; acepromazine.
ATC vet code: QN05AA04

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Sodium Acetate
Sodium Cyclamate
Hydroxyethylcellulose(4500-6000)
Glycerol (85 per cent)
Purified Water

6.2 Major incompatibilities

None known.

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^{o}C.

6.5 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: 10ml homogenous yellow-orange aqueous gel.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/057/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 2000
Date of last renewal: 30th September 2010

10 DATE OF REVISION OF THE TEXT

August 2019