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Sedalin 35mg /ml Oral Gel

Species: Horses and other equidae

Therapeutic indication:Pharmaceuticals: Neurological preparations: Tranquilisers

Active ingredient: Acepromazine Maleate

Product: Sedalin 35mg/ml oral Gel

Product index: Sedalin oral gel

Withdrawal notes: Not authorised for use in horses intended for human consumption.

Incorporating:

Presentation

Yellow-orange transparent gel for oral administration. Each ml contains acepromazine (as acepromazine maleate) 35.0 mg and methyl-4-hydroxybenzoate 0.65 mg and propyl-4-hydroxybenzoate 0.35 mg as preservatives.

Uses

For sedation of horses

Dosage and administration

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.

Contra-indications, warnings, etc

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

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.

Special precautions for use in animals

Do not use in cases of post traumatic hypovolemia.

Operator warning

In the 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.

Adverse reactions (frequency and seriousness)

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

Use during pregnancy or lactation

Acepromazine should not be used in pregnant or lactating mares.

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

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.

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.

Withdrawal period

Not authorised for use in horses intended for human consumption.

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.

Keep out of reach of children.

Do not store above 25°C.

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

Legal category

Legal category:POM-V

Packaging quantities

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

Further information

ATC Vet Code: QN05AA04. 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.

Marketing Authorisation Number

UK (GB): Vm 08007/5020

UK (NI): Vm 06462/3011

Significant changes

GTIN

GTIN description: Sedalin Gel

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