PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON
SEDALIN 35MG / ML ORAL GEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedalin 35mg/ml ORAL GEL

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance
Acepromazine 35.0mg (Acepromazine Maleate equivalent)
List of Excipients
Methyl-4-hydroxybenzoate 0.65 mg and Propyl-4-hydroxybenzoate 0.35 mg

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

10 ml tube.

5. TARGET SPECIES

Horse.

6. INDICATION(S)

For sedation in horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Each oral doser contains 10 ml and is graduated at 1ml intervals.
Moderate sedation: 0.15mg Acepromazine /kg bodyweight.

8. WITHDRAWAL PERIOD

Not authorised for use in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications and warnings:
Not for use in animals in shock or post-traumatically, or with existing severe emotional excitation or epilepsy. For further warnings see package leaflet.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For oral administration only. For animal treatment only.
UK authorised veterinary medicinal product.
To be supplied only on veterinary prescription.
POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep all medicines out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufacturer:
Vetoquinol BIOWET Ltd.
Kosynierow Gdynskich Str. 13-14
66-400 Gorzow Wlkp, Poland

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 08007/4089

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - LABEL
SEDALIN 35MG / ML ORAL GEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedalin 35mg/ml ORAL GEL

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance
Acepromazine 35.0mg (Acepromazine Maleate equivalent)
List of Excipients
Methyl-4-hydroxybenzoate 0.65 mg and Propyl-4-hydroxybenzoate 0.35 mg

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

10ml tube.

5. TARGET SPECIES

Horse.

6. INDICATIONS

For sedation of horses.

7. METHOD AND ROUTE OF ADMINISTRATION

Moderate sedation: 0.15mg Acepromazine /kg bodyweight.

8. WITHDRAWAL PERIOD

Not authorised for use in horses intended for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

For administration, contra-indications and user warnings see package leaflet.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For oral administration only.
For animal treatment only.
UK authorised veterinary medicinal product.
To be supplied only on veterinary prescription.

POM-V

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep all medicines out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4089

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PACKAGE LEAFLET

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 Maleate BP Vet)
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 use

4. CLINICAL PARTICULARS

4.1 Target species

Horse.

4.2 Indications for use, specifying the target species

For sedation in horses.
(Relaxation of horses, Sedation in cases of nervousness, muscle contractions, (tetany, lumbago), stressful situations and for transport).

4.3 Contra-indications

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

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.
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.

4.5 Special precautions for use

(i) Special precautions for use in animals

Do not use in cases of post-traumatic hypovolemia. Sedation lasts for approximately six hours, although the actual time and depth of sedation are very dependent on the status of the individual animal.

(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 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 irritations 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.

4.7 Use during pregnancy, lactation or lay

SEDALIN GEL should not be used during pregnant or lactating mares. In stallions the lowest dose range is indicated to minimize prolapse of the penis.

4.8 Interaction with other medicinal products and other forms of interaction

Acepromazine potentiates the action of centrally depressant drugs. Organophosphates increase the toxicity of Acepromazine. Simultaneous administration or administration to patients who were treated recently with organophosphates should be avoided. Since Acepromazine decreases sympathetic nervous system tone, it should not at the same time as blood-pressure reducing drugs.

4.9 Amounts to be administered and administration route

Each oral doser is graduated at 1ml intervals.

Moderate sedation: 0.15 mg acepromazine / kg bodyweight (2ml/ 450kg).

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.

4.9 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdose results in an earlier onset of the sedative symptoms 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.

4.10 Withdrawal period(s)

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

Pharmacotherapeutic Group:

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.4. Special precautions for storage

Do not store above 25ºC. Keep the container in the outer carton.

6.5 Nature and composition of immediate packaging

10 ml polyethylene syringe

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

7. MARKETING AUTHORISATION HOLDER

Manufacturer:
Vetoquinol BIOWET Ltd.
Kosynierow Gdynskich Str. 13-14
66-400 Gorzow Wlkp, Poland

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

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4089

9. DATE OF FIRST AUTHORISATION

25 March 1996

10. DATE OF REVISION OF THE TEXT

May 2018

Other information:

For animal treatment only. Keep all medicines out of the reach of children.
To be supplied only on veterinary prescription.
POM-V
Legal category:
UK authorised veterinary medicinal product

Approved 02 May 2018