PARTICULARS TO APPEAR ON THE OUTER PACKAGE

20 ml carton folding box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedivet 10 mg/ml solution for injection for horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Romifidine hydrochloride 10 mg

Chlorocresol 2 mg (as antimicrobial preservative)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

Sedative to facilitate handling, examination, minor surgical interventions and manipulations. Sedivet may be used to facilitate handling, for minor surgical procedures and as a pre-anaesthetic agent prior to ketamine or thiopentone. For profound analgesia/sedation, use with synthetic opiates.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For i.v. use only. 0.4 – 1.2 ml/100 kg (40 – 120 µg romifidine HCl/kg).

Should not be used in horses in the last month of pregnancy.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 6 days.

Not authorised for use in lactating animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Operator warnings: Alpha 2-adrenoreceptor agonists can cause severe adverse reactions. You must read the warnings on the package leaflet before using this product.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Shelf-life of broached vial: 28 days.

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 animal treatment only.

To be supplied only on veterinary prescription

UK	POM-V
IE	VPO

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBERS

UK: Vm 08327/4302

IE: VPA 10454/013/001

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20ml glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedivet 10 mg/ml solution for injection for horses

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Romifidine hydrochloride 10 mg

Chlorocresol 2 mg (as antimicrobial preservative)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTE(S) OF ADMINISTRATION

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For i.v. use only. 0.4 – 1.2 ml/100 kg (40 – 120 µg romifidine HCl/kg).

Should not be used in horses in the last month of pregnancy.

Read the package leaflet before use.

6. WITHDRAWAL PERIOD

Meat and offal: 6 days.

Not authorised for use in lactating animals producing milk for human consumption.

7. BATCH NUMBER

Lot:

8. EXPIRY DATE

Exp:

9. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

10. FURTHER INFORMATION

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer responsible for batch release:

Labiana Life Sciences S.A.

Venus 26

Can Parellada Industrial

08228 Terrassa

Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedivet 10 mg/ml solution for injection for horses

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each ml contains:

Romifidine hydrochloride 10 mg

Chlorocresol 2 mg (as antimicrobial preservative)

4. INDICATION(S)

Sedative to facilitate handling, examination, minor surgical interventions and manipulations.

Sedivet may be used as a premedication agent with ketamine or thiopentone for short duration anaesthesia, or used with ketamine or thiopentone prior to halothane inhalation or ‘topping up’ with ketamine or thiopentone for prolonged procedures.

Sedivet has also been used with synthetic opiates (eg. butorphenol) to provide profound sedation/analgesia.

5. CONTRAINDICATIONS

The product should not be used in horses in the last month of pregnancy.

6. ADVERSE REACTIONS

As with other drugs of this class, administration may cause bradycardia, which may be profound, benign reversible cardiac arrhythmia with second degree heart block and hypotension. These effects may be prevented by the administration of 0.01 mg/kg atropine 5 minutes prior to administration of the sedative. These effects are usually well-tolerated but care should be taken in patients with cardiovascular disease. Incoordination of the limbs and sweating may also occur.

Hyperglycaemia and diuresis may accompany sedation.

In very rare cases hypersensitivity may occur.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intravenous use only. A dose range of 0.4 – 1.2 ml Sedivet/100 kg bodyweight (equivalent to 40 to 120 micrograms romifidine HCl/kg) gives a dose-related response.

Onset of action, which is independent of dose, is 1 – 2 minutes. Maximum sedation is achieved after 5 – 10 minutes. Please the Chart below

Recommended dose

Sedation

Dose	Depth of Sedation	Duration of Sedation
0.4 ml Sedivet/100 kg bodyweight (ie. 40 micrograms romifidine/kg bodyweight)	Light	0.5–1 hour
0.8 ml Sedivet/100 kg bodyweight (ie. 80 micrograms romifidine/kg bodyweight)	Deep	0.5–1.5 hours

1.2 ml Sedivet/100 kg bodyweight (ie. 120 micrograms romifidine/kg of sedation bodyweight)	Deep sedation of prolonged duration	At this dose residual sedation may persist for up to 3 hours

To reduce the possibility of unexpected defensive movements such as kicking, a dose of 0.4 – 1.2 ml per 100 kg bodyweight (equivalent to 40– 120 micrograms romifidine HCl/kg) followed by 0.2 ml Torbugesic per 100 kg bodyweight (equivalent to 20 micrograms butorphanol/ kg) should be administered intravenously. (An average dose of 0.6 ml Sedivet and 0.2 ml Torbugesic has been found to be effective in the majority of horses, although this may vary between individuals).

Premedication

Premedication with ketamine for induction

When used prior to ketamine induced anaesthesia, with or without halothane, a dose rate of 1 ml/100 kg (equivalent to 100 micrograms romifidine HCl/kg bodyweight) should be used followed by 2.2 mg/kg ketamine after 5 to 10 minutes.

Premedication with other agents for induction

When used with other anaesthetic agents, a dose of 0.4 – 0.8 ml per 100 kg bodyweight has been found to be most suitable. This corresponds to 40 to 80 micrograms romifidine HCl/kg bodyweight. Anaesthesia should be induced after maximum sedation is achieved (5 – 10 minutes).

Maintenance of anaesthesia

Anaesthesia may be maintained using halothane in oxygen by inhalation. Should maintenance of surgical anaesthesia be required when facilities for gaseous anaesthesia are not available, this can be achieved by ‘topping up’ doses of romifidine/ketamine or thiopentone.

Ketamine

To maintain or deepen surgical anaesthesia with romifidine/ketamine, administer the product intravenously at a dose of 0.25 ml/100 kg bodyweight (25 micrograms/kg romifidine HCl) followed immediately by ketamine intravenously at a dose of 1.1 mg/kg (Vetalar 1.1 ml/100 kg). Administer the romifidine/ketamine top-up dose immediately prior to commencement of surgical incision or when signs of returning consciousness appear.

Thiopentone

Thiopentone may be used after romifidine/ketamine or romifidine/thiopentone induction at a dose of 0.25 g/100 kg bodyweight. This should be administered when signs of returning consciousness appear. This can be repeated up to 3 times after the induction dose.

9. ADVICE ON CORRECT ADMINISTRATION

For intravenous use only.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 6 days.

When used in combination with other products, consult the product literature of those products and apply whichever is the longer. However, if any of these products is contra-indicated for human consumption, then treated animals must not be slaughtered for human consumption. Not authorised for use in lactating animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 25° C.

Shelf-life after first opening the container: 28 days.

Do not use after the expiry date (EXP) stated on the carton and bottle.

12. SPECIAL WARNING(S)

Precautions for use in animals

In common with other sedatives of this class, defensive movements, i.e. kicking, may occur even in apparently well sedated animals. These occurrences may be reduced by the use of opiates, e.g. butorphanol.

When used as a pre-anaesthetic agent, sedation should be apparent before the induction of anaesthesia.

When the product is used as part of the anaesthetic procedure, care should be taken during the recovery phase to ensure that the horse is kept in a warm and quiet environment.

Precautions to be taken by the person administering the product

In the case of accidental oral intake or self injection, seek medical advice immediately and show the package leaflet to the doctor but DO NOT DRIVE as sedation and changes in blood pressure may occur.

Avoid skin, eye or mucosal contact.

Immediately after exposure, wash the exposed skin with large amounts of fresh water.

Remove contaminated clothes that are in direct contact with skin.

In the case of accidental contact of the product with eyes, rinse with large amounts of fresh water. If symptoms occur, seek the advice of a doctor.

If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Advice to doctors:

Romifidine is an alpha-2-adrenoreceptor agonist, symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.

Interactions

The sedative effect of the product may be potentiated by other psychoactive compounds, such as tranquillisers, other sedatives or morphine-like analgesics, therefore reducing the required dose of subsequent anaesthetic agents.

The concurrent i.v. use of potentiated sulphonamides with alpha-2-agonists has been reported to cause cardiac arrhythmias which may be fatal. Whilst no such effects have been reported with Sedivet, it is recommended that i.v. administration of TMP/S containing products should not be undertaken when horses have been sedated with Sedivet.

Overdose

Dosages up to 5 times the highest recommended dose caused transient adverse reactions, such as sweating, bradycardia, second degree atrioventricular heart blocks, hypotension, ataxia, hyperglycaemia and diuresis. In case of overdose with an alpha-2 adrenergic agonist or should the effects become toxic, symptomatic treatment should be initiated or an alpha-2 adrenergic antagonist can be used for reducing such effects.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2020

15. OTHER INFORMATION

20 ml

Legal category

UK: POM-V To be supplied only on veterinary prescription.

Ireland VPO Veterinary Practitioner Only

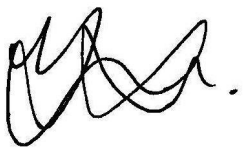
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Veterinary Medicinal Product authorised for use in UK and IE.

Vm 08327/4302

VPA 10454/013/001

Sedivet is a registered trademark of Boehringer Ingelheim Vetmedica GbmH, used under licence.



Approved: 31 March 2020