SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedivet 10 mg/ml solution for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Romifidine hydrochloride 10mg
equivalent to 8.76 mg romifidine

Preservative
Chlorocresol 2mg

For a full list of excipients, please see 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
Clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

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

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

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

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

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 alpha2-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.

4.6 Adverse reactions (frequency and seriousness)

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 0.01mg/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.

4.7 Use during pregnancy, lactation or lay

Not to be used in horses in the last month of pregnancy.

4.8 Interactions with other medicinal products and other forms of interaction

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.

4.9 Amount to be administered and administration route.

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 see 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 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 0.2ml Torbugesic per 100kg 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 0.25ml/100 kg bodyweight (25 micrograms/kg romifidine) followed immediately by ketamine intravenously at a dose of 1.1mg/kg (Vetalar 1.1ml/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 0.25g/100 kg bodyweight. This should be administered when signs of returning consciousness appear. This can be repeated upto 3 times after the induction dose.

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

Dosages upto 5 times the highest recommended dose caused transient adverse reactions, such as sweating, bradycardia, second degree atrio-ventricular heart blocks, hypotension, ataxia, hyperglycaemia and diuresis. In case of overdose, adverse reactions, as listed in section 4.6, are expected to be more severe and more frequent.

In such cases, symptomatic treatment should be initiated; an alpha-2 adrenergic antagonist may be useful in reducing such effects.

4.11 Withdrawal period

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.

5. PHARMACOLOGICAL PROPERTIES

Romifidine is an alpha-2-agonist of the imino-imidazolidine class
Pharmacotherapeutic group: Hypnotics and sedatives

ATC vet code: QN05CM93

5.1 Pharmacodynamic properties

Romifidine exerts sedative and analgesic effects. Its sedative effect is induced by stimulation of alpha-2-adrenoreceptors in the central nervous system. The substance possesses a strong specific affinity for these receptors.

5.2 Pharmacokinetic properties

Absorption
Since Sedivet is recommended to be administered intravenously, its active ingredient is completely bioavailable.

Distribution:
Approximately 20% of romifidine is bound to plasma proteins. The highest drug concentrations are to be found in the liver and kidney.

Metabolism:
Romifidine is found predominantly in kidney and muscle, whereas liver contains only traces of the parent compound. The major metabolites present in urine and tissues are SHT 2130, STH 2337 and ESR 1235, which have been shown to be pharmacologically inactive.

Elimination:
Romifidine is rapidly eliminated: approximately 80% of the administered dose is via urine and the remainder via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Chlorocresol
Water for injections

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf-life of the medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate product: 28 days.

6.4 Special precautions for storage

Do not store above 25ºC

6.5 Nature and composition of immediate packaging

20ml clear Type I PhEur glass vial with grey bromobutyl stopper.

6.6 Special precuations for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate.

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

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 08327/5064

9. DATE OF FIRST AUTHORISATION

15 October 1991

10. DATE OF REVISION OF THE TEXT

August 2025

Gavin Hall
Approved: 28 August 2025