SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rominervin 10 mg/ml solution for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorocresol	2 mg
Sodium chloride	
Hydrochloric acid, diluted (for pH adjustment)	
Sodium hydroxide (for pH adjustment)	
Water for injections	

Clear colourless to slight yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses

3.2 Indications for use for each target species

Sedative to facilitate handling, examination, minor surgical interventions and minor procedures.
For premedication prior to administration of injectable or inhalation anaesthetics.
Romifidine can also be used with synthetic opiates (e.g. butorphanol) to provide deeper sedation/analgesia.

3.3 Contraindications

Do not use in horses in the last month of pregnancy.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use Trimethoprim-Sulfonamide-containing products intravenously when horses have been sedated with romifidine.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Sedation with α2 agonist drugs, such as romifidine may increase the sensitivity of the hind legs to tactile stimuli. Occasionally, defensive reactions, i.e. kicking, may occur even in apparently well sedated animals.
The veterinary medicinal product should be used with caution in animals suffering from cardiovascular or respiratory diseases, hepatic or renal insufficiency and in animals in shock.
When used as a pre-anaesthetic agent, sedation should be apparent before the induction of anaesthesia.
When the veterinary medicinal 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 ingestion or self-injection, seek medical advice immediately and show the package leaflet to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur.
Avoid skin, eye or mucosal contact.
Wash the exposed skin immediately after exposure with large amounts of water.
Remove contaminated clothes that are in direct contact with skin.
In the case of accidental contact of the veterinary medicinal product with eyes, rinse thoroughly with fresh water. If symptoms occur, seek the advice of a physician.
If pregnant women handle the veterinary medicinal product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

To the physician:
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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Colic (mild)[a] Hypersensitivity reaction Ataxia[b], increased sensitivity[c]
Undetermined frequency (cannot be estimated from the available data):	Bradycardia[d], arrhythmia (heart block 2nd degree, sino-atrial block)[e], hypotension[f], hypertension[f] Increased sweating Increased salivation Hyperglycaemia Polyuria Penile prolapse (partial)[g]

[a] As the intestinal motility is temporarily inhibited.
[b] Incoordination of the limbs.
[c] Of the hind legs (defensive movements).
[d] May be profound.
[e] Benign, reversible.
[f] Short period of hypertension, followed by hypotension.
[g] Reversible.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during the last month of pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

The sedative effect of the veterinary medicinal 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 intravenous use of potentiated sulphonamides with alpha2-agonists has been reported to cause cardiac arrhythmias which may be fatal. Intravenous administration of TMP/S containing veterinary medicinal products is therefore contra-indicated when horses have been sedated with romifidine.

The concomitant use of romifidine and phenothiazines (e.g. acepromazine) can result in severe hypotension.
The veterinary medicinal product should not be used in association with other substances belonging to the same pharmacological class (sympathicomimetic amines, including alpha-2-agonist, such as xylazine, detomidine..).

3.9 Administration routes and dosage

Intravenous use.
A dose range of 0.04 – 0.12 mg romifidine HCl/kg bodyweight (0.4 – 1.2 ml veterinary medicinal product per 100 kg bodyweight) 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 Table below.

Recommended dose

Sedation

Dose	Depth of Sedation	Duration of Sedation
0.04 mg romifidine HCl/kg bw (i.e. **0.4 ml veterinary medicinal product/100 kg** bw)	Light	0.5 - 1 hour
0.08 mg romifidine HCl/kg bw (i.e. **0.8 ml veterinary medicinal product/100 kg** bw)	Deep	0.5 – 1.5 hours
0.12 mg romifidine HCl/kg bw (i.e. **1.2 ml veterinary medicinal product/100 kg** bw)	Deep sedation of prolonged duration	At this dose residual sedation may persist for up to 3 hours

When romifidine is used in combination with butorphanol for deeper sedation and analgesia, a dose of 0.04 mg – 0.12 mg romifidine HCl/kg bw (0.4 – 1.2 ml veterinary medicinal product per 100 kg bw) should be used followed by butorphanol.

Premedication

Premedication with ketamine for induction
When romifidine is used as premedication prior to ketamine induced anaesthesia, a dose of 0.1 mg romifidine HCl/ kg bw (1 ml veterinary medicinal product per 100 kg bw) should be used followed by ketamine after 5 – 10 minutes.

Premedication with other agents for induction
When romifidine is used as premedication in combination with other agents such as injectable or inhalation anaesthetics, a dose of 0.04 mg – 0.08 mg romifidine HCl/kg bw (0.4 – 0.8 ml veterinary medicinal product per 100 kg bw) should be used followed by induction of anaesthesia after 5 – 10 minutes.

Maintenance of anaesthesia

To maintain or deepen surgical anaesthesia with romifidine/ketamine, when facilities for gaseous anaesthesia are not available, romifidine can be administered at a dose of 0.025 mg/kg romifidine HCl (0.25 ml veterinary medicinal product per 100 kg bodyweight) followed immediately by ketamine intravenously (50 % of the initial ketamine premedication dose). Administer the romifidine/ketamine top-up dose immediately prior to commencement of surgical incision or when signs of returning consciousness appear.

The stopper should not be punctured more than 40 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Dosages up to 5 times the highest recommended dose caused transient adverse events, such as sweating, bradycardia, second degree atrio-ventricular heart blocks, hypotension, ataxia, hyperglycaemia and diuresis.
In case of overdose, adverse events, as listed in section 3.6 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 6 days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN05CM93

4.2 Pharmacodynamics

Romifidine is an alpha-2-agonist of the imino-imidazolidine class. It 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.
After administration of romifidine, blood pressure increases initially due to its effect on peripheral postsynaptic α1-receptors in combination with activation of extrajunctional α2b-adrenoceptors located on smooth muscle cells in the arteriolar resistance vessels. Subsequently, blood pressure decreases due to the effect on peripheral presynaptic receptors (inhibition of noradrenaline release from sympatic nerve endings) and decrease of sympathetic tone resulting in vasodilatation.

4.3 Pharmacokinetics

Approximately 20 % of romifidine is bound to plasma proteins. Romifidine is found predominantly in the kidney and muscle, whereas the liver contains only traces of the parent compound. The main hepatic metabolites, SHT 2130, STH 2337 and ESR 1235, have been shown to be pharmacologically inactive.
Following intravenous injection, romifidine is rapidly eliminated: approximately 80 % of the administered dose is eliminated via urine and the remainder via the faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 56 days.

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Colourless type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap. One glass vial in a cardboard box.

Pack size
Box with 1 vial 10 ml.
Box with 1 vial of 20 ml.
Box with 1 vial of 50 ml.

Multi-pack with 6 boxes each containing 1 vial of 10 ml.
Multi-pack with 6 boxes each containing 1 vial of 20 ml.
Multi-pack with 6 boxes each containing 1 vial of 50 ml.

Multi-pack with 10 boxes each containing 1 vial of 10 ml.
Multi-pack with 10 boxes each containing 1 vial of 20 ml.
Multi-pack with 10 boxes each containing 1 vial of 50 ml.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 41821/4062

8. DATE OF FIRST AUTHORISATION

24 October 2018

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

July 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 11 August 2026