

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND**

**Outer carton for 10, 20 and 50 ml vials and outer carton of multi-packs**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Rominervin 10 mg/ml solution for injection for horses  
romifidine hydrochloride

**2. STATEMENT OF ACTIVE SUBSTANCES**

romifidine hydrochloride 10 mg/ml  
(equivalent to romifidine 8.76 mg)

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

10 ml  
20 ml  
50 ml  
6 x 10 ml  
6 x 20 ml  
6 x 50 ml  
10 x 10 ml  
10 x 20 ml  
10 x 50 ml

**5. TARGET SPECIES**

Horses



**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For intravenous use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal periods(s)

Meat and offal: 6 days.

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

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Shelf life after first opening the bottle: 56 days

Once broached use by...

**11. SPECIAL STORAGE CONDITIONS**

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

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

Disposal: read package leaflet

**13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only.

Supply / use: (National issue)

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Le Vet Beheer B.V.  
Wilgenweg 7  
3421 TV Oudewater  
The Netherlands

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 41821/4062

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Glass vials of 10, 20 or 50 ml**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Rominervin 10 mg/ml solution for injection for horses  
romifidine hydrochloride



**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

10 mg/ml

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

10 ml  
20 ml  
50 ml

**4. ROUTE(S) OF ADMINISTRATION**

IV

**5. WITHDRAWAL PERIOD(S)**

Withdrawal periods(s)  
Meat and offal: 6 days.  
Not authorised for use in animals producing milk for human consumption.

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}  
Shelf life after first opening the container: 56 days  
Once broached use by .....

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET:

### Rominervin 10 mg/ml solution for injection for horses

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

Marketing authorisation holder:

Le Vet Beheer B.V.  
Wilgenweg 7  
3421 TV Oudewater  
The Netherlands

Manufacturer responsible for batch release:

Produlab Pharma B.V.  
Forellenweg 16  
4941 SJ Raamsdonksveer  
The Netherlands

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rominervin 10 mg/ml solution for injection for horses  
romifidine hydrochloride

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

Each ml contains

**Active substance:**

Romifidine hydrochloride            10 mg  
equivalent to 8.76 mg romifidine

**Excipient(s):**

Chlorocresol                            2 mg

Clear colourless to slight yellow solution.

#### 4. INDICATION(S)

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.



## **5. 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 TMP/S-containing products intravenously when horses have been sedated with romifidine.

## **6. ADVERSE REACTIONS**

As with other veterinary medicinal products of this class, the following adverse events may occur:

- Bradycardia, which may be profound
- Benign, reversible cardiac arrhythmias (second degree AV block and to a lesser extent sino-atrial block)
- Hypotension, following a short period of hypertension
- Incoördination of the limbs/ataxia
- Sweating and increased salivation
- Hyperglycemia and diuresis
- In male horses, a reversible, partial penile prolapse can occur.
- Increased sensitivity of the hind legs (defensive movements)
- In very rare cases mild symptoms of colic, as the intestinal motility is temporarily inhibited.

Hypersensitivity may occur in very rare cases.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}

## **7. TARGET SPECIES**

Horses.

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

For intravenous use. A dose range of 0.04 – 0.12 mg romifidine HCl/kg bodyweight (0.4 – 1.2 ml product/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. <b>0.4 ml product/100 kg bw</b> )	Light	0.5 - 1 hour
0.08 mg romifidine HCl/kg bw (i.e. <b>0.8 ml product/100 kg bw</b> )	Deep	0.5 – 1.5 hours
0.12 mg romifidine HCl/kg bw (i.e. <b>1.2 ml product/100 kg bw</b> )	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 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 product/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 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 product/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.

## **9. ADVICE ON CORRECT ADMINISTRATION**

The stopper should not be punctured more than 40 times

## **10. WITHDRAWAL PERIOD(S)**

Meat and offal: 6 days.

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

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the bottle: 56 days

## **12. SPECIAL WARNING(S)**

### Special precautions for use in animals:

Sedation with  $\alpha_2$  agonist drugs, such as romifidine may increase the sensitivity of the hind legs to touch. 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 oral intake or self-injection, seek medical advice immediately and show the package insert 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 product with eyes, rinse thoroughly with fresh water. If symptoms occur, seek the advice of a physician.

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 the physician:

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.

### Pregnancy and Lactation:

Do not use during the last month of pregnancy.

Overdose (symptoms, emergency procedures, antidotes):

Dosages up to 5 times the highest recommended dose caused transient adverse reactions, such as sweating, bradycardia, second degree atrio-ventricular heart blocks, hypotension, ataxia, hyperglycaemia and increase in 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.

Interactions:

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 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 product should not be used in association with other substances belonging to the same pharmacological class (sympathomimetic amines, including alpha-2-agonist, such as xylazine, detomidine..).

Incompatibilities:

Do not mix with any other veterinary medicinal product.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS**

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

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

DD-MM-YYYY

**15. OTHER INFORMATION**

Pack sizes:

Cardboard box with 1 vial of 10 ml, 20 ml or 50 ml.

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

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

Not all pack sizes may be marketed.

Approved 03 March 2023

