PARTICULARS TO APPEAR ON THE OUTER PACKAGE – Outer Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormazolam 5 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Midazolam 5.0 mg

Excipients:
Benzyl alcohol (E1519) 10.0 mg

3. PACKAGE SIZE

5 ml
10 ml
20 ml
50 ml

4. TARGET SPECIES

Horses

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal period(s):
Not authorised for use in horses intended for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days
Once broached, use by:

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

14. MARKETING AUTHORISATION NUMBERS

Vm 50406/5009

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

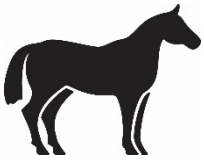
18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS - Glass vials of 5, 10, 20 or 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormazolam 5 mg/ml solution for injection



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}:
Once broached use within 28 days
Once broached, use by:

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

5 ml
10 ml
20 ml
50 ml

6. ROUTE(S) OF ADMINISTRATION

IV

7. WITHDRAWAL PERIOD

Withdrawal period(s):
The product is not authorised for use in horses intended for human consumption.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only. POM-V

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dormazolam 5 mg/ml solution for injection for horses

2. COMPOSITION

Each ml contains:

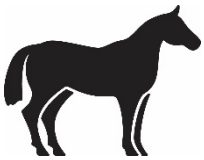
Active substance:
Midazolam 5.0 mg

Excipient(s):
Benzyl alcohol (E1519) 10.0 mg

Clear, colourless solution.

3. TARGET SPECIES

Horses



4. INDICATIONS FOR USE

Intravenous co-induction of anaesthesia with ketamine for smooth induction and intubation and profound muscle relaxation during anaesthesia.

5. CONTRAINDICATIONS

Do not use in animals with severe respiratory failure.

Do not use as a sole agent in horses.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. SPECIAL WARNING(S)

Special precautions for use in target species:

In case of renal or hepatic dysfunction or respiratory depression there may be greater risk associated with the use of the veterinary medicinal product. Use only according to the benefit/risk assessment by the responsible veterinarian.

Midazolam produces muscle relaxation; when used as a sole agent horses may be slightly sedated, but also restless or even agitated when they become ataxic/unstable.

Prolonged recovery time (prolonged recumbence and time to extubation) may be associated with use of the product.

The safety of repeated bolus dosing (at 0.06 mg/kg) at intervals of less than 4 days has not been established. Based on the pharmacokinetics of the active substance, care should be taken when administering repeated doses of midazolam within a 24-hour period to horses, particularly neonatal foals (i.e. foals less than 3 weeks old), obese horses and horses with hepatic impairment or conditions associated with reduced organ perfusion, due to the possibility of drug accumulation.

Care should be taken when administering the product to hypoalbuminaemic horses since these animals may have higher sensitivity to a given dose.

Before using combinations of midazolam with other veterinary medicinal products, the product literature for the other products should be observed.

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

Midazolam is a CNS depressant and can cause sedation and induction of sleep. Care should be taken to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician, but DO NOT DRIVE as sedation and impaired muscular function may occur.

Midazolam and its metabolites may be harmful for the unborn child, and are secreted into breastmilk in small amounts, thereby exerting a pharmacological effect on the nursing neonate. Pregnant and breastfeeding women should, therefore, take great care when handling this product and, in the event of exposure, seek medical advice immediately.

People with known sensitivity to midazolam or the excipients should avoid contact with the veterinary medicinal product.

This product contains benzyl alcohol and can cause skin irritation. Avoid contact with skin. In the case of contact with skin, wash with soap and water. If irritation persists, seek medical advice. Wash hands after use.

The product can cause eye irritation. Avoid contact with eyes. If the product comes into contact with the eyes, rinse the eyes immediately with plenty of water and seek medical attention if irritation persists.

Advice to physicians:
Like other benzodiazepines, midazolam commonly causes drowsiness, ataxia, dysarthria anterograde amnesia, and nystagmus. Overdose of midazolam is seldom life-threatening if the drug is taken alone, but may lead to areflexia, apnoea, hypotension, cardiorespiratory depression and in rare cases to coma.

Monitor the patient's vital signs and institute supportive measures as indicated by the patient's clinical state. Respiratory and haemodynamic symptoms should be treated symptomatically.

Pregnancy and lactation:
Laboratory studies in mice, rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. In humans, use of benzodiazepines during the late third trimester of pregnancy or during labour has been associated with adverse effects in the foetus/neonate, including mild sedation, hypotonia, reluctance to suck, apnoea, cyanosis and impaired metabolic response to cold stress.
Midazolam is found in low quantities in the milk of lactating animals.

The safety of the veterinary medicinal product during pregnancy and lactation has not been established in horses. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction:

Midazolam potentiates the effect of some sedative and anaesthetic agents, reducing the dose required, including alpha-2-agonists (detomidine, xylazine), propofol and some inhalational agents.

Concurrent use of midazolam with antihistamines (H_2-receptor antagonists, e.g. cimetidine), barbiturates, local anaesthetics, opioid analgesics or CNS depressants may enhance the sedative effect.

In combination with other agents (e.g. opioid analgesics, inhalational anaesthetics), an increase in respiratory depression may be observed.

Erythromycin and azole antifungals (fluconazole, ketoconazole) inhibit the metabolism of midazolam, resulting in increased plasma midazolam concentrations and increased sedation.

Drugs that induce CYP450 mediated metabolism, such as rifampin, may decrease plasma concentrations and effects of midazolam.

Overdose:
The symptoms of overdose are mainly an intensification of the pharmacological effects of midazolam: drowsiness, and muscle relaxation.

In case of accidental midazolam overdose, restlessness or agitation in combination with prolonged muscle weakness may develop when the ketamine effect of the combined midazolam-ketamine anaesthesia subsides.

Following a dose of 0.18 mg midazolam per kg bodyweight (3 times overdose) in combination with ketamine (2.2 mg/kg intravenously) after premedication with detomidine (20 µg/kg intravenously) the following effects attributable to midazolam were observed: poor recovery (more attempts to stand, more ataxia), a slight decrease of the haematocrit, respiratory depression - evidenced by a slight decrease of the respiratory rate, a lower pO_2, a metabolic alkalosis and a slight increase of arterial pH - and a prolonged recovery. A dose of 0.3 mg midazolam per kg bodyweight (5 times overdose) using the same combination resulted in a violent

recovery, i.e. horse trying to stand up, whilst still having profound muscle weakness.

The benzodiazepine antagonist flumazenil can be used to reverse effects associated with an overdose of midazolam, although clinical experience in horses is limited.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except with ketamine 100 mg/ml solution for injection.

For Animal Treatment Only.

7. ADVERSE EVENTS

Target species: Horses

Common (1 to 10 animals / 100 animals treated):	Ataxia, incoordination. *
Uncommon (1 to 10 animals / 1,000 animals treated):	Respiratory depression, urination.**

*during recovery from anaesthesia
**upon induction of anaesthesia

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

For intravenous use.

Once the horse is properly sedated, anaesthesia is induced by intravenous injection of:
Midazolam at a dose of 0.06 mg per kg body weight, corresponding to 1.2 ml solution per 100 kg, in combination with ketamine at a dose of 2.2 mg per kg body weight.

9. ADVICE ON CORRECT ADMINISTRATION

Midazolam and ketamine may be combined and administered in the same syringe.

10. WITHDRAWAL PERIOD(S)

Not authorised for use in horses intended 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 and label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 28 days
This veterinary medicinal product does not require any special temperature storage conditions.
Once the container is broached, using the shelf-life after first opening, calculate the discard date and record in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation number(s):
50406/5009

Packaging:
Colourless type I glass vials of 5 ml, 10 ml, 20 ml and 50 ml closed with a coated bromobutyl rubber stopper and aluminium cap in a carton box.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

March 2024

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

17. OTHER INFORMATION

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

Approved 04 March 2024