PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING LABEL=LEAFLET

500 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Myorelax 100 mg/ml solution for infusion for horses
Guaifenesin

2. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml contains:
Active substance:
Guaifenesin 100 mg

3. PHARMACEUTICAL FORM

Solution for infusion.
Clear, colourless to light brown solution for infusion.

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Horses.

6. INDICATIONS

Induction of muscle relaxation and immobilisation, as an adjunct to balanced anaesthesia.
Depending on the procedure, guaifenesin can be used in combination with different anaesthetics:

- in combination with a sedative, and local anaesthetics for short procedures
- in combination with appropriate general anaesthetics, for induction and/or maintenance of muscle relaxation during anaesthesia

7. CONTRAINDICATIONS

None.

8. ADVERSE REACTIONS

Guaifenesin may lower arterial blood pressure. Due to its irritative properties, use of the veterinary medicinal product may result in thrombophlebitis. To reduce the incidence of thrombophlebitis, the catheter can be flushed with heparinised saline. Extravascular reactions have been reported; the use of an intravenous catheter and a careful technique will help prevent such occurrences.
If you notice any serious effects or other effects not mentioned on this labelling, please inform your veterinary surgeon.

9. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION, AND ADVICE ON CORRECT ADMINISTRATION

For intravenous administration by catheter.
Dose: 100 mg guaifenesin per kg body weight per infusion, equivalent to 100 ml solution per 100 kg body weight.
Guaifenesin can be used in combination with different anaesthetics, as follows:
Local anaesthetics for short procedures:
Once the horse is properly sedated, guaifenesin is administered by rapid infusion until the animal lies down. A local anaesthetic should be used for painful procedures. Additional guaifenesin can be infused when the horse is recumbent, if needed.
General anaesthetics:

- *Induction and short term maintenance of anaesthesia:*

Pre-medication with an α-2 receptor agonist (e.g. xylazine, detomidine or romifidine) or acepromazine. If guaifenesin is to be administered with ketamine, pre-medication with one of the α-2 receptor agonists is recommended.
Guaifenesin is administered by rapid infusion until the animal begins to sway on its feet. at this stage either ketamine, thiopental or propofol is administered at a bolus dose. The duration of action of these combinations is variable depending on the animal and the other drugs administered. Surgical anaesthesia will be approximately 10-20 minutes duration and recumbency will be approximately 30-40 minutes duration.

- *Maintenance of anaesthesia for medium duration procedures:*

Guaifenesin, administered by continuous IV infusion (50-100 mg/kg) at an infusion rate of approximately 1 ml/kg/h, can be used as part of total intravenous anaesthesia (TIVA) in combination with other injectable anaesthetics for procedures lasting up to 1 hour.

- *Volatile anaesthetics:*

Guaifenesin can be used as an adjunct to balanced anaesthesia using volatile anaesthetics for longer procedures.

Guidance on anaesthetic protocols and doses of individual veterinary medicinal products can be found in veterinary textbooks and scientific literature. For safe use with other pharmaceuticals, reference must be made to the relevant product literature.

10. WITHDRAWAL PERIOD

Not authorised for use in horses intended for human consumption.

11. SPECIAL WARNINGS

Special warnings for each target species:
Guaifenesin should not be used alone. Animals must be properly sedated before immobilisation with the veterinary medicinal product. Adequate analgesia should always be provided for surgical and/or painful procedures.
Animals should undergo a thorough pre-anaesthetic examination before administration of the product. Except in the case of an acute emergency, feed should be withheld for 12 hours prior to anaesthesia. Water should be freely available until a short time before anaesthesia.

Special precautions for use in animals:
Due to the irritative effects of the solution, it should be administered strictly intravenously using a catheter. See also section 'Adverse reactions'.
Animals with anaemia, cardiac or respiratory problems, or animals with other signs of disease should be monitored extra carefully.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to guaifenesin should avoid contact with the veterinary medicinal product. Take care to avoid skin or eye contact. In case of accidental skin contact wash affected area thoroughly. If irritation occurs/persists, seek medical advice. In case of accidental eye contact flush thoroughly with clean water and seek medical advice immediately, showing the product label to the physician.
Use during pregnancy or lactation:
Guaifenesin crosses the placenta, but no short term negative effects on the foetus were observed. The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Therefore, use only according to the benefit/risk assessment by the responsible veterinarian.
Interactions with other medicinal products and other forms of interaction:
The action of anaesthetic agents is potentiated by guaifenesin.
Overdose (symptoms, emergency procedures, antidotes)
Doses greater than those needed to obtain recumbency may result in significant respiratory depression. Signs of overdose, e.g. extensor spasms, occur at approximately twice the therapeutic dose. The lethal dose is four times the recommended treatment dose.
Incompatibilities:
Do not mix with any other veterinary medicinal product.

12. EXPIRY DATE

EXP: {month/year}
Shelf life after first opening the immediate packaging: Use immediately.

13. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

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

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

15. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. Administration by a veterinarian only.

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

Keep out of the sight and reach of children.

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

Marketing authorisation holder and manufacturer responsible for batch release
Eurovet Animal Health B.V.
Handelsweg 25,
5531 AE Bladel,
The Netherlands

18. MARKETING AUTHORISATION NUMBER

Vm 16849/4041

19. MANUFACTURER’S BATCH NUMBER

Lot: {number}

20. DATE ON WHICH THE TEXT WAS LAST APPROVED

August 2017

21. OTHER INFORMATION

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
=
OUTSIDE OF THE TEAR OPEN LABEL

500 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Myorelax 100 mg/ml solution for infusion for horses
Guaifenesin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:
Guaifenesin 100 mg

3. PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless to light brown solution for infusion.

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Horses.

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

For intravenous administration by catheter.
Read the package leaflet before use

8. WITHDRAWAL PERIOD

Not authorised for use in horses intended for human consumption.

9. SPECIAL WARNINGS

Read the package leaflet before use

10. EXPIRY DATE

EXP: {month/year}
Once opened: Use immediately.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

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

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

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

For animal treatment only. Administration by a veterinarian only.

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

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15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.
Handelsweg 25,
5531 AE Bladel,
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 16849/4041

17. MANUFACTURER’S BATCH NUMBER

Lot: {number}

PACKAGE LEAFLET FOR:
Myorelax 100 mg/ml solution for infusion 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 and manufacturer responsible for batch release:
Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Myorelax 100 mg/ml solution for infusion for horses
Guaifenesin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml contains:
Active substance:
Guaifenesin 100 mg

4. INDICATIONS

Induction of muscle relaxation and immobilisation, as an adjunct to balanced anaesthesia.
Depending on the procedure, guaifenesin can be used in combination with different anaesthetics:

- in combination with a sedative, and local anaesthetics for short procedures
- in combination with appropriate general anaesthetics, for induction and/or maintenance of muscle relaxation during anaesthesia.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Guaifenesin may lower arterial blood pressure.
Due to its irritative properties, use of the veterinary medicinal product may result in thrombophlebitis. To reduce the incidence of thrombophlebitis, the catheter can be flushed with heparinised saline. Extravascular reactions have been reported; the use of an intravenous catheter and a careful technique will help prevent such occurrences.

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

7. TARGET SPECIES

Horses.

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

For intravenous administration by catheter:
Dose: 100 mg guaifenesin per kg body weight per infusion, equivalent to 100 ml solution per 100 kg body weight.

Guaifenesin can be used in combination with different anaesthetics, as follows:
Local anaesthetics for short procedures:
Once the horse is properly sedated, guaifenesin is administered by rapid infusion until the animal lies down. A local anaesthetic should be used for painful procedures. Additional guaifenesin can be infused when the horse is recumbent, if needed.

General anaesthetics:
- *Induction and short term maintenance of anaesthesia:*

Pre-medication with an α-2 receptor agonist (e.g. xylazine, detomidine or romifidine) or acepromazine. If guaifenesin is to be administered with ketamine, pre-medication with one of the α-2 receptor agonists is recommended.
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- *Maintenance of anaesthesia for medium duration procedures:*

Guaifenesin, administered by continuous IV infusion (50-100 mg/kg) at an infusion rate of approximately 1 ml/kg/h, can be used as part of total intravenous anaesthesia (TIVA) in combination with other injectable anaesthetics for procedures lasting up to 1 hour.
- *Volatile anaesthetics:*

Guaifenesin can be used as an adjunct to balanced anaesthesia using volatile anaesthetics for longer procedures.

Guidance on anaesthetic protocols and doges of individual veterinary medicinal products can be found in veterinary textbooks and scientific literature.
For safe use with other pharmaceuticals, reference must be made to the relevant product literature.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Not authorised for use in horses intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: Use immediately.

12. SPECIAL WARNINGS

Special warnings for each target species:
Guaifenesin should not be used alone. Animals must be properly sedated before immobilisation with the veterinary medicinal product. Adequate analgesia should always be provided for surgical and/or painful procedures.
Animals should undergo a thorough pre-anaesthetic examination before administration of the product. Except in the case of an acute emergency, feed should be withheld for 12 hours prior to anaesthesia. Water should be freely available until a short time before anaesthesia.

Special precautions for use in animals:
Due to the irritative effects of the solution, it should be administered strictly intravenously using a catheter. See also ‘Adverse reactions’, section 6.
Animals with anaemia, cardiac or respiratory problems, or animals with other signs of disease should be monitored extra carefully.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to guaifenesin should avoid contact with the veterinary medicinal product.
Take care to avoid skin or eye contact. In case of accidental skin contact wash affected area thoroughly. If irritation occurs/persists, seek medical advice. In case of accidental eye contact flush thoroughly with clean water and seek medical advice immediately, showing the product label to the physician.

Use during pregnancy or lactation:

Guaifenesin crosses the placenta, but no short term negative effects on the foetus were observed. The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Therefore, use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
The action of anaesthetic agents is potentiated by guaifenesin.

Overdose (symptoms, emergency procedures, antidotes):
Doses greater than those needed to obtain recumbency may result in significant respiratory depression. Signs of overdose, e.g. extensor spasms, occur at approximately twice the therapeutic dose. The lethal dose is four times the recommended treatment dose.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2017

15. OTHER INFORMATION

Pack size: 500 ml.

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

Approved: 30 August 2017