SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Myorelax 100 mg/ml solution for infusion for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substance:Guaifenesin 100 mg
Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Clear, colourless to light brown solution for infusion.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 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.

4.5 Special precautions for use

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 4.6.
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.

4.6 Adverse reactions (frequency and seriousness)

Guaifenesin may lower arterial blood pressure.
Due to the 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.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

The action of anaesthetic agents is potentiated by guaifenesin.

4.9 Amounts to be administered and administration route

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.

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

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.

4.11 Withdrawal period

Not authorised for use in horses intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Centrally acting muscle relaxant.
ATCvet code: QM03BX90.

5.1 Pharmacodynamic properties

Guaifenesin is a centrally acting muscle relaxant. It causes a selective, reversible relaxing of the skeletal muscles, without loss of consciousness. Guaifenesin selectively blocks nerve impulse transmission in the binding neurons of the spinal cord, brainstem and subcortical regions of the brain. Spinal monosynaptic pathways are unaffected by therapeutic dosages of guaifenesin.

Pharyngeal and laryngeal muscles relax, but when therapeutic doses are administered, no paralysis of the respiratory muscles (intercostal muscles and diaphragm) occurs. The effect on vital functions such as circulation and breathing is slight.

In addition to its muscle relaxing effect, guaifenesin also has a sedative effect. Guaifenesin has only limited analgesic properties. These effects are probably the result of guaifenesin acting on the extended medulla (formatio reticularis, among others) and subcortical regions of the brain. Due to the limited analgesic and sedative properties of guaifenesin (the animal retains full consciousness), animals must be properly sedated before immobilisation with guaifenesin.

5.2 Pharmacokinetic particulars

In the case of ponies, a significant difference in half-life between female and male animals has been observed: 60 and 84 minutes respectively after parenteral administration.

In horses, half-life averaged between 75.7-79.2 minutes.

The substance is uniformly distributed over most tissues. Concentrations in the blood of the neonate were approximately 30% that of the mother immediately after birth.

The muscle relaxing effect starts on average within a few minutes.

The effect of guaifenesin lasts approximately 8-20 minutes. Animals stand again within 45 minutes after administration. The recovery period lengthens substantially after repeated administrations.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose monohydrate
N-methylpyrrolidone
Water for injections
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf life after first opening the immediate packaging: Use immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

500 ml polypropylene bottle with a bromobutyl rubber stop and aluminium cap.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 16849/4041

9. DATE OF FIRSTAUTHORISATION

31 August 2012

10. DATE OF REVISION OF THE TEXT

August 2017

CONDITIONS OR LIMITATIONS WITH RESPECT TO DELIVERY AND USE

Administration by a veterinarian only.

Approved: 30 August 2017