

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10966/020/001**

Case No: 7006390

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Vetoquinol UK Limited

Vetoquinol House, Great Slade, Buckingham MK18 1PA, United Kingdom

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Myolaxin 15% solution for infusion

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **30/09/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Myolaxin 15% solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Guaifenesin 15.00% w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for infusion.

A clear nearly colourless to faintly yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses declared as not being intended for slaughter for human consumption.

4.2 Indications for use, specifying the target species

A muscle relaxant for medicamentous casting and sedation.

4.3 Contraindications

Do not use in case of known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Horses should be fasted for 12 hours prior to use.

Myolaxin does lower the arterial blood pressure, but casting with Myolaxin can be considered safer and smoother than with other narcosis techniques (mononarcosis with Thiobarbiturate). In case of faulty infusion techniques and partial paravenous infusion, thrombophlebitis must be reckoned with.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Myolaxin can be safely used in pregnant mares.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

Administration is by intravenous injection.

Infuse 60 - 80 ml/100 kg bodyweight within 2 minutes. This infusion is accelerated by pressing the bag.

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

None.

4.11 Withdrawal Period(s)

Treated horses may never be slaughtered for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Muscolo-skeletal system, muscle relaxants, centrally acting agents, guaifenesin.

ATC vet code: QM03BX90

Guaifenesin is a centrally acting muscle relaxant of the mephenesin type which blocks the internuncial neurons within the brain stem and the spinal cord. Myolaxin 15% causes sedation and relaxation of the skeletal muscle in a dose dependant manner.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous Glucose
Propylene Glycol
N-Methyl Pyrolidone
Sodium Hydroxide
Water for Injections

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf life of the veterianry medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Do not freeze or refrigerate.
Protect from light.

6.5 Nature and composition of immediate packaging

500 ml low density polyethylene form/fill/seal bag with a port cap closed with a natural rubber disc.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited,
Vetoquinol House,
Great Slade,
Buckingham Industrial Park,
Buckingham,
MK18 1PA,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10966/020/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT