

IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10966/017/001**
Case No: 7002007

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) 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:

Atussin Syrup

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.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: 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

Atussin Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances

Dextromethorphan Hydrobromide	0.500 % w/v
Chlorphenamine Maleate	0.071 % w/v
Guaifenesin	0.900 % w/v
Ephedrine Hydrochloride	0.500 % w/v

Excipients

Methyl Parahydroxybenzoate	0.065 % w/v
Propyl Parahydroxybenzoate	0.035 % w/v
Ethanol (96 per cent)	0.400 % w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Syrup

4 CLINICAL PARTICULARS

4.1 Target Species

Dog

4.2 Indications for use, specifying the target species

As an aid in symptomatic relief of cough

4.3 Contraindications

Do not use in case of hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product should not be used in pregnant or lactating animals unless deemed essential by the veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Recommended dose for oral administration 1 - 3 ml (30 to 90 drops), two to three times a day, or as directed by the veterinarian.

If no response is seen after 5 days treatment the diagnosis should be re-determined.

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

No case of overdose has been reported.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

All four active ingredients act on the respiratory system in combination:

Dextromethorphan is a specific antitussive to help reduce unproductive cough by increasing the cough threshold but not eliminating it completely or reducing the mucosal cilia movement which is of importance in clearing bronchial passageways or secretion.

Guaifenesin, through its blocking of inter neuronal pathways assist in this process and where bronchial secretion is viscous, dry or insufficient, guaifenesin is a secrolytic or mucolytic - it increases secretion and thereby reduces the viscosity of the sputum. This secrolytic action of guaifenesin together with the decongestant action of ephedrine assists breathing while the CNS stimulation of respiration by ephedrine further aids improved respiration. Mucosal swelling or congestion is also a common feature of respiratory infections, impairing respiratory function by reducing airflow. To counter this effect, ephedrine is included for its vaso-constrictive effects and for its ability to stimulate circulation. Histamine mediated constriction of the bronchi is a further complication of a respiratory infection. This constriction is caused by dust, pollen, fungal spores and other allergens and by the inflammatory process itself, resulting in bronchial spasm.

Chlorpheniramine blocks the histamine on the one hand while ephedrine relaxes the bronchial smooth muscle.

Guaifenesin may also contribute in this regard through its muscular relaxation action.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Ethanol (96 per cent)
Molasses
Glycerol (85 per cent)
Sorbitol (70 per cent) (non-crystallising)
Anise Oil
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf-life

24 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

White LDPE bottles with screw caps containing viscous brown, clear or slightly opaque syrup.
Package sizes: bottle with 60 ml

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

Unused product or waste material should be disposed of in accordance with current practise for pharmaceutical waste under national waste disposal regulations.

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 10996/17/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10th June 2004.