

IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10983/017/001**
Case No: 7002050

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 Ireland Limited

Unit B, Oranmore Business Park, Oranmore, Galway, Ireland

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:

Frecardyl Solution for Injection

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

Frecardyl Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances

Heptaminol Hydrochloride 62.6 mg

Diprophylline 50.0 mg

Excipients

Methyl Parahydroxybenzoate (E218) 1.0 mg

Propyl Parahydroxybenzoate (E216) 0.2 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Neo-natal foals, calves, piglets, dogs, cats.

4.2 Indications for use, specifying the target species

Cardio-respiratory analeptic.

4.3 Contraindications

Do not use in animals with known hypersensitivity to one of the ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Avoid contact with eyes and skin. In case of accidental contact or injection flush immediately with water and/or consult a doctor at once.

4.6 Adverse reactions (frequency and seriousness)

This product may cause positive reaction to anti-drug controls.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

For intramuscular use only.

2 ml per 10 kg of bodyweight.

The treatment may be repeated 4 to 5 hours later and for 4 to 5 days.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat: 7 days.

Milk: Not indicated for animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Frecardyl stimulates and restores the normal activity of the circulatory and respiratory functions while acting simultaneously on heart, vessels and respiration.

It combines:

HEPTAMINOL HYDROCHLORIDE: Heart and respiratory stimulant, it increases the tonus of the heart muscle, it acts as vasodilator and diuretic. Heptaminol Hydrochloride also prevents fatigue of muscle and nervous activities.

DIPROPHYLLINE: A derivate of theophylline, its analeptic and cardiorespiratory action stimulates the central cortex and the vagal, vasomotor and respiratory bulber centres. It induces relaxation of bronchial spasm, dilates coronary arteries, stimulates respiration and myocardium, and increases cardiac flow.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Sodium Hydroxide
Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

24 months. In-use expiry date: 28 days.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

50 ml Type II amber glass vial closed with a rubber stopper.

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 practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

VETOQUINOL Ireland Limited
Wilton Place
Dublin 2

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10983/17/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004