

**IRISH MEDICINES BOARD ACT 1995**

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

**(S.I. No. 786 of 2007)**

VPA: **10793/001/001**

Case No: 7005654

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:

**Acravet Ltd**

**IDA Industrial Estate, Pulleen, Co. Cork, 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:

**Delta Apomorphine Hydrochloride Solution for Injection 3 mg/ml**

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 **07/02/2007**.

Signed on behalf of the Irish Medicines Board

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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

Delta Apomorphine Hydrochloride Solution for Injection 3 mg/ml

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

##### Active Substance

Apomorphine Hydrochloride 3 mg/ml

##### Excipients:

Sodium metabisulphite 1 mg/ml

For a full list of excipients, see section 6.1

#### 3 PHARMACEUTICAL FORM

Solution for injection.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Dog

##### 4.2 Indications for use, specifying the target species

Delta Apomorphine Hydrochloride Solution for injection BP (Vet.) is indicated for use as an emetic, in dogs.

##### 4.3 Contraindications

Do not use in cases of depression of the central nervous system. Use is contra-indicated in cats.

##### 4.4 Special warnings for each target species

Do not exceed the recommended dosage. If emesis is not induced following a single injection, repeated injections will also prove ineffective and so should not be given.

##### 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

In the case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.

#### **4.6 Adverse reactions (frequency and seriousness)**

At higher doses apomorphine may suppress vomiting and cause depression.

#### **4.7 Use during pregnancy, lactation or lay**

No data are available. Use only according to the benefit/risk assessment by the responsible veterinarian.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

No data are available.

#### **4.9 Amounts to be administered and administration route**

Dogs: 0.05 – 0.10 mg (0.02 – 0.03 ml) per kg bodyweight, by subcutaneous injection.

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

Not applicable

#### **4.11 Withdrawal Period(s)**

Not applicable

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Apomorphine induces emesis by stimulation of the dopamine D<sub>2</sub>-receptors in the chemoreceptor trigger zone (CTZ). Apomorphine may lower blood pressure.

#### **5.2 Pharmacokinetic properties**

Slower absorption on subcutaneous administration maintains apomorphine concentrations during the first three – ten minutes lower and at a range sufficient to induce emesis, by stimulating the D<sub>2</sub>-receptors of the CTZ, but not high enough to stimulate the opiate  $\mu$ -receptors within the vomiting centre which moderate an anti-emetic effect.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Sodium Metabisulphite  
Sodium Chloride  
Water for Injections

#### **6.2 Incompatibilities**

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

### **6.3 Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years. Once opened, use immediately.

### **6.4 Special precautions for storage**

Do not store above 25°C.

Protect from light.

Do not use if the solution has turned green.

### **6.5 Nature and composition of immediate packaging**

Cardboard box containing five 1 ml clear glass (Ph. Eur. type I) ampoules.

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

Any unused medicinal product should be disposed of in accordance with local requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Acravet Ltd.,  
IDA Industrial Estate,  
Pulleen,  
Kanturk,  
Co. Cork.

## **8 MARKETING AUTHORISATION NUMBER(S)**

10793/001/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

7<sup>th</sup> February 2007

## **10 DATE OF REVISION OF THE TEXT**