IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10823/019/001**
Case No: 7007641

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:

Chem-Pharm

Ballyvaughan, **Co. Clare**, **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:

Lignocaine & Adrenaline 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.

The authorisation, unless previously revoked, shall continue in force from **16/04/2010**.

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

Lignocaine & Adrenaline Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances	
Lidocaine Hydrochloride	20 mg
Epinephrine Acid Tartrate	0.027 mg
(equivalent to Adrenaline)	0.0125 mg
Excipients	
Chlorocresol (preservative)	1 mg
Sodium metabisulphite (antioxidant)	1 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses.

4.2 Indications for use, specifying the target species

For infiltration anaesthesia (local or field block) and regional anaesthesia.

4.3 Contraindications

Do not administer by intravenous injection.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Local infiltration of the product may delay wound healing.

4.7 Use during pregnancy, lactation or lay

Lignocaine and Adrenaline Injection can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

For subcutaneous and intramuscular injection only.

1. Local infiltration and field block anaesthesia:
   Up to 100 - 200 ml per surgical site

2. Regional anaesthesia:
   Up to 7 ml per site.

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

In mild cases of overdose, animals may become anxious and restless. The symptoms are transient and will pass off with little or no treatment being necessary.

In severe cases of overdose convulsions may occur and respiratory and circulatory failure may follow. Overdosage may be treated by administering respiratory stimulants and keeping animals warm.

4.11 Withdrawal Period(s)

Horses may be slaughtered for human consumption only after 28 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anaesthetics, Local; lidocaine, combinations
ATCvet code: QN01BB52

Lidocaine is an aminoacyl amide and an effective local analgesic. When administered locally it prevents conduction of the nerve impulse by disrupting the migration of sodium ions across the nerve membrane. Adrenaline acts as a vasoconstrictor when administered locally and therefore delays the absorption of Lidocaine from the site of action, and prolongs the analgesic effect.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride
Sodium Metabisulphite
Chlorocresol
Water for Injection

6.2 Incompatibilities

In the absence of compatibility studies this veterinary medicinal product should 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 the vial has been broached the contents should be used within 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

Lignocaine and Adrenaline Injection is marketed in 100 ml and 500 ml amber Type II glass vials, closed with bromobutyl rubber bungs, and aluminium overseals.

Not all pack sizes may be marketed.

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

Chem-Pharm Ltd.
Ballyvaughan
Co. Clare

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10823/019/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16th April 2010

10 DATE OF REVISION OF THE TEXT