IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) REGULATIONS 2007

(S.I. No. 144 of 2007)

VPA: **10823/015/001**
Case No: 7002642

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 144 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:

Calcipharm 40 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 **01/10/2006**.

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

Calcipharm 40 Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substances

Calcium Gluconate (as calcium borogluconate)	332 mg
Boric Acid	68 mg

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
A clear pale yellow sterile aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Calcipharm 40 is indicated in the treatment of hypocalcaemia in cattle.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The solution should be warmed to body temperature before administration. Intravenous injections should be given slowly and stopped on the first signs of adverse reaction. As intravenous administration of this product could cause death, this route should only be used by a veterinary surgeon.

Special Precautions to be taken by the Person Administering the Product to Animals

None.

4.6 Adverse reactions (frequency and seriousness)

Rapid intravenous injection may result in cardiac arrhythmias and collapse and death in severely toxaemic animals.

4.7 Use during pregnancy, lactation or lay

Calcipharm 40 can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administer by subcutaneous or slow intravenous injection.

Cattle: 150 - 400 ml.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat: nil
Milk: nil

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Milk fever which is characterised by hypocalcaemia is caused by an acute drop in the level of ionised calcium. Administration of calcium borogluconate by subcutaneous or slow intravenous injection replenishes plasma calcium levels and reverses the hypocalcaemia.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Bicarbonate
Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
2 years.

6.4 Special precautions for storage

Store at less than 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

400 ml Type III glass vials (amber) sealed with rubber wads (black) and aluminium screw caps.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Chem-Pharm Ltd
Ballyvaughan
Co Clare
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10823/15/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2006

10 DATE OF REVISION OF THE TEXT

5th July 2007