

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10823/014/001**

Case No: 7002643

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:

Calcipharm PMD 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

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 PMD Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Calcium Gluconate	166 mg
Boric Acid	34 mg
Dextrose monohydrate	200 mg
Magnesium hypophosphite (as hexahydrate)	50 mg

Excipient:

Chlorocresol (as preservative)	1 mg
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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

Sheep

4.2 Indications for use, specifying the target species

Calcipharm PMD is indicated in the treatment of hypocalcaemia complicated by a deficiency of Magnesium with accompanying hypoglycaemia.

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 at the first signs of adverse reaction. Rapid intravenous injection may result in cardiac arrhythmias and collapse and death in severely toxæmic animals.

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)

None known.

4.7 Use during pregnancy, lactation or lay

Calcipharm PMD 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.

Sheep: 50 - 80 ml

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

Not applicable.

4.11 Withdrawal Period(s)

Meat: Nil. Animals intended for human consumption may be slaughtered following treatment.

Milk: Nil. Milk intended for human consumption may be taken from animals during treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Milk fever, characterised by hypocalcaemia is caused by an acute drop in the level of calcium in the blood. At parturition, hypophosphataemia and hypomagnesaemia can also occur. Calcipharm PMD administered by subcutaneous or slow intravenous injection replenishes plasma concentrations of calcium, phosphate and magnesium ions. Dextrose is included as an energy source to coincide with the high turnover of energy at lambing.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
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.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

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

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

None.

7 MARKETING AUTHORISATION HOLDER

Chem-Pharm Ltd
Ballyvaughan
Co Clare
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10823/14/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2001 / 1st October 2006