

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject PMD Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Calcium Gluconate	166 mg
Boric Acid	34 mg
Dextrose Monohydrate	200 mg
Magnesium Hypophosphite (as hexahydrate)	50 mg

Excipients

Chlorocresol (as preservative) 1 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

Sheep.

4.2 Indications for use, specifying the target species

Calciject 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

No special warnings.

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, in severely toxæmic animals, collapse and death. 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

Calciject PMD can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

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

Milk: Nil

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. Calciject 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 Major 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, or 400 ml polypropylene containers sealed with bromobutyl bungs (grey) and aluminium caps.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/029/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1991

Date of last renewal: 01 October 2006

10 DATE OF REVISION OF THE TEXT

January 2019