Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject LV Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substances	
Calcium Gluconate	388.5 mg
Boric Acid	73.4 mg
Magnesium Chloride Hexahydrate	65.0 mg
Calcium Hydroxide	13.2 mg

(equivalent to 42 mg calcium, 7.8 mg magnesium and 73.4 mg boric acid per ml)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless to pale yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Calciject LV is indicated in the treatment of hypocalcaemia in cattle complicated by a deficiency of magnesium.

In cases of acute hypomagnesaemia the administration, by appropriate routes, of a solution of higher magnesium concentration may be necessary.

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

Calciject LV does not contain an antimicrobial preservative. Any solution remaining in the vial following withdrawal of required dose should be discarded.

Solutions for intravenous injection should be warmed to body temperature and infused slowly.

Sternal recumbency as a result of hypocalcaemia is often associated with poor peripheral circulation. Calcium therapy by intravenous injection is more appropriate in these cases.

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 veterinary medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

Rapid intravenous injection may result in cardiac arrythmias and, in severely toxaemic cows, collapse and death.

4.7 Use during pregnancy, lactation or lay

Calciject LV is safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

Not applicable.

4.9 Amounts to be administered and administration route

Slow intravenous injection or subcutaneous injection.

Dosage: 100 - 200 ml.

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

Rapid intravenous injection may result in cardiac arrythmias or heart block. Therefore intravenous
injections should be given slowly and stopped on the first signs of adverse reaction

4.11 Withdrawal period(s)

Meat: Zero days.

Milk: Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dietry supplements and fluid metabolites.

ATC Vet Code : QA12AC

5.1 Pharmacodynamic properties

Calcium borogluconate, calcium hydroxide and magnesium chloride hexahydrate are soluble salts of calcium and magnesium respectively, used extensively in fluid metabolite preparations. On parenteral administration they rapidly increase plasma concentrations of calcium and magnesium. This is effective in the treatment of hypocalcaemia with associated hypomagnesaemia.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phosphoric Acid
Water for Injections
Sodium Hydroxide

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Any unused material should be discarded following opening.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

Calciject LV is packaged in 100 ml clear grade II glass vials and also in 100 ml amber grade II glass vials with bromobutyl bungs 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 poduct 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)

VPA22664/044/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 March 1996
Date of last renewal: 21 March 2006

10 DATE OF REVISION OF THE TEXT

January 2019