

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject 20 CM Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each 400 ml contains 5.92g Calcium (provided by Calcium Gluconate and Calcium Borogluconate) and 1.85g magnesium (provided by magnesium hypophosphite). Also contains 3.23% w/v boric acid.

Excipients:

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.
Sheep

4.2 Indications for use, specifying the target species

For the treatment of hypocalcaemia in cattle complicated by a deficiency of magnesium in cattle and sheep.

4.3 Contraindications

None.

4.4 Special Warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

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

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

Care should be taken to avoid accidental self-injection.

4.6 Adverse reactions (frequency and seriousness)

Rapid intravenous injection may result in cardiac arrhythmias and in severely toxæmic cows, collapse and death.

4.7 Use during pregnancy, lactation or lay

Provided the necessary precautions are observed the product should be safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Slow intravenous injection.

Subcutaneous injection.

Massage site gently after administration

Cattle	:	400 - 800 ml
Sheep	:	50 - 80 ml

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

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

4.11 Withdrawal period

Cattle

Meat	:	Zero Days
Milk	:	Zero Hours

Sheep

Meat	:	Zero Days
Milk	:	Zero Hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Metabolic Preparation

ATC Vet Code: QA12AX

5.1 Pharmacodynamic properties

Calcium Borogluconate and Magnesium Hypophosphite are soluble salts of calcium and magnesium respectively used extensively in fluid metabolite preparations. On parenteral administration they rapidly increase plasma concentrations of calcium, magnesium and phosphorus. This is effective in the treatment of hypocalcaemia with associated (hypomagnesaemia).

5.2 Pharmacokinetic properties

The absorption of magnesium takes place in the proximal small intestine by active transport in a common pathway with calcium. Magnesium ions are inefficiently absorbed from the gastro-intestinal tract where absorption may be enhanced by the presence of vitamin D. Magnesium salts are excreted mainly in the urine with small amounts in milk, saliva and faeces. The normal range for magnesium in large animals is 1.7-3.0mg/100ml and clinical signs appear when the level drops below 1.0mg/100ml.

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:
Glass bottles: 2 years, Polypropylene vials: 18 months

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.
Any solution remaining in the vial following withdrawal of the required dose should be discarded.

6.5 Nature and composition of immediate packaging

Marketed in either 400 ml Amber Type III glass vials sealed using black rubber wads and aluminium screw caps, or 400ml polypropylene containers sealed with bromobutyl bungs and aluminium caps.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4120

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15th November 1994/15th November 2004

10. DATE OF REVISION OF TEXT

February 2008