SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Downland Low Volume Calcium Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance(s)

Each 100 ml contains 4.2g calcium (provided by calcium gluconate, calcium borogluconate and calcium hydroxide) and 0.78g magnesium (provided by magnesium chloride hexahydrate). Also contains 7.34% w/v boric acid.

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

Indicated in the treatment of hypocalcaemia in cattle complicated by a deficiency of magnesium.

4.3 Contraindications

None

4.4 Special Warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

The product 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.

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

Care should be taken to avoid accidental self-injection: may cause irritation at site of injection.

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

Provided the above 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 recorded.

4.9 Amounts to be administered and administration route

Slow intravenous injection

Subcutaneous injection.
Massage the site gently after administration.

Dosage: Cattle - 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

Cattle - Meat: Zero Days
Milk: Zero Hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Metabolic & Fluid Preparation

ATC Vet Code: QA12AA20

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.

5.2 Pharmacokinetic properties

After injection of Downland Low Volume Calcium, plasma levels of calcium and magnesium were recorded at 2.51 $\pm$ 0.039 mmol/L and 0.889 $\pm$ 0.041 mmol/L respectively which are within the normal ranges for plasma calcium and magnesium.

Mean C_{max} values for calcium of 4.2 $\pm$ 0.08 mmol/L were obtained following administration of Calicject LV. The corresponding mean AUC values for calcium were 61.38 $\pm$ 0.59 mmol/L.hr

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phosphoric Acid, Concentrated.
Sodium Hydroxide
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

Do not store above 25ºC.
Protect from light.
This product does not contain an antimicrobial preservative. Any solution remaining in the vial following withdrawal of the required dose should be discarded.

6.5 Nature and composition of immediate packaging

Carton containing 8 x 100 ml clear colourless glass Type II vial with rubber bromobutyl bung with aluminium overseal.

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
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm: 02000/4291

9. DATE OF RENEWAL OF AUTHORISATION

3 August 2010

10. DATE OF REVISION OF THE TEXT

September 2010