

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Downlands Calcium Borogluconate 40% w/v CM Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each ml contains:

400 mg Calcium Borogluconate and 50 mg Magnesium Hypophosphite Hexahydrate.

Each 400 ml contains:

11.9 g calcium (provided by calcium gluconate and calcium borogluconate) and 1.85 g magnesium hypophosphite hexahydrate)

Also contains 6.84% w/v boric acid.

Excipients:

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection

A clear pale yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

Treatment of hypocalcaemia in cattle where increased blood magnesium levels are required.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i) Special precautions for use in animals

The solution should be warmed to body temperature before administration. Intravenous injections should be given slowly in order to avoid possible neuromuscular dysfunction and cardiac insufficiency. Normal aseptic precautions should be observed. Sites of subcutaneous administration should be massaged gently.

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

Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical advice.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Occasional temporary swelling may occur at sites of subcutaneous administration.

4.7 Use during pregnancy, lactation or lay

Safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None

4.9 Amount(s) to be administered and administration route

Administer by subcutaneous or slow intravenous injection

Cattle : 200 - 400 ml

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

Not applicable.

4.11 Withdrawal period(s)

Meat and offal: Zero days

Milk: Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Mineral supplements, Calcium, Calcium, combinations with other drugs

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 infusions in correction of metabolic disturbances. On parenteral administration they rapidly increase plasma concentrations of calcium, magnesium and phosphorus. This is effective in the treatment of hypocalcaemia with associated magnesium and phosphorus deficiencies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Bicarbonate 10% or Boric Acid 5% (for pH adjustment)
Water for Injections

6.2 Major Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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.
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

The product is 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
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4214

9. DATE OF FIRST AUTHORISATION

05 July 1999

10. DATE OF REVISION OF THE TEXT

July 2018

Approved: 27 July 2018

A handwritten signature in black ink, appearing to read 'D. Austin', with a horizontal line extending from the end of the signature.