

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

400 mg Calcium Borogluconate and 50 mg Magnesium Hypophosphite Hexahydrate.

Each 400 ml contains 11.9g calcium (provided by calcium gluconate and calcium borogluconate) and 1.85g magnesium (provided by magnesium hypophosphite). Also contains 6.84% w/v boric acid.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

400 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Downlands Calcium Borogluconate 40% CM is indicated in the treatment of hypocalcaemia in cattle where increased blood magnesium levels are also required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By subcutaneous or slow intravenous injection.

Cattle: 200 - 400 ml

8. WITHDRAWAL PERIOD

Meat and offal: Zero days

Milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

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

Normal aseptic precautions should be observed.

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.
Sites of subcutaneous administration should be massaged gently.

User Warnings: Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical advice. Wash hands after use.

10. EXPIRY DATE

EXP.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

Manufacturer:

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

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ, Co Down
Northern Ireland

On behalf of:

Downland Marketing Ltd
Main Mill
Warwick Mill Business Centre
Warwick Bridge
Carlisle
CA4 8RR
Phone: 01228 564498
Email: bestadvice@downland.co.uk

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4214

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

PACKAGE LEAFLET FOR:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each ml contains:

400 mg Calcium Borogluconate and 50 mg Magnesium Hypophosphite Hexahydrate.

A clear pale yellow solution

Each 400 ml contains:

11.9g calcium (provided by calcium gluconate and calcium borogluconate) and 1.85g magnesium (provided by magnesium hypophosphite) and 6.84% w/v boric acid.

4. INDICATION(S)

Downlands Calcium Borogluconate 40% CM is indicated in the treatment of hypocalcaemia in cattle where increased blood magnesium levels are also required.

5. CONTRAINDICATIONS

Normal aseptic precautions should be observed. Sites of subcutaneous administration should be massaged gently.

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

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

By subcutaneous or slow intravenous injection.

Cattle: 200-400 ml.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Meat and offal: Zero days

Milk: Zero hours

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Protect from light

Keep out of the reach and sight of children.

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

12. SPECIAL WARNING(S)

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.

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2022

15. OTHER INFORMATION

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription

Package Quantities:

Containers of 400 ml.

Marketing Authorisation no.:

Vm. 02000/4214

Manufacturer's Licence No.:

ManA 2000

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ, Co Down
Northern Ireland

On behalf of:

Downland Marketing Ltd
Main Mill
Warwick Mill Business Centre
Warwick Bridge
Carlisle
CA4 8RR
Phone: 01228 564498
Email: bestadvice@downland.co.uk

Approved: 03 January 2023