

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

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
Newry
Co. Down, BT35 6JP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject 20 CM Solution for Injection

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

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.

4. PHARMACEUTICAL FORM

Solution for injection

5. PACKAGE SIZE

400 ml

6. INDICATION(S)

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

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

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

9. TARGET SPECIES

Cattle and sheep

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

By subcutaneous injection or slow intravenous injection, massage site gently after administration

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

11. ADVICE ON CORRECT ADMINISTRATION

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

12. WITHDRAWAL PERIOD

Cattle

Meat : Zero Days
Milk : Zero Hours

Sheep

Meat : Zero Days
Milk : Zero Hours

13. SPECIAL STORAGE PRECAUTIONS

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

Calciject 20 CM does not contain an antimicrobial preservative. Any solution remaining in the vial following withdrawal of the required dose should be discarded.

14. SPECIAL WARNING(S)

The solution should be warmed to body temperature before administration.
Intravenous injections should be given slowly.

Care should be taken to avoid accidental self-injection.

15. EXPIRY DATE

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Rinse containers thoroughly with water. Dispose of rinsings in slurry or dirty water. Dispose of rinsed containers in the farm refuse. Used containers should not be recycled.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

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

[Distribution category]

For animal treatment only. To be supplied only on veterinary prescription

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| POM- VPS |
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19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

20. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4120

21. MANUFACTURER’S BATCH NUMBER

Approved: 10/01/2018

