Reviewed: May 2017 AN: 00366/2017

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

Manufactured by:

Norbrook Laboratories Limited Newry Co. Down BT35 6JP

Distributed by:

Norbrook Laboratories (GB) Limited 1 Saxon Way East Oakley Hay Industrial Estate Corby Northamptonshire NN18 9EX United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject 20CMD Solution for Injection

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

Contains Calcium Borogluconate 20% w/v, Magnesium Hypophosphite Hexahydrate 5% w/v and Glucose Monohydrate 22% w/v.

Each 400ml contains:

5.92g calcium (provided by calcium gluconate and calcium borogluconate), 1.84g magnesium (provided by magnesium hypophosphate hexahydrate) and 80g glucose as glucose monohydrate. Also contains 3.40% w/v boric acid.

4. PHARMACEUTICAL FORM

Solution for Injection

5. PACKAGE SIZE

400ml

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6. INDICATION(S)

For the treatment of hypocalcaemia complicated by deficiency of magnesium with accompanying hypoglycaemia, in sheep. In the treatment of pregnancy, toxaemia and other metabolic imbalances in periparturient sheep.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Sheep

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

For subcutaneous injection only SHEEP 50 - 80 ml

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Sheep – Meat/Milk: Zero days/hours

13. SPECIAL STORAGE PRECAUTIONS

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

14. SPECIAL WARNING(S)

The solution should be warmed to body temperature before administration.

Not to be administered by intravenous or intramuscular routes.

Massage site gently after administration.

Care should be taken to avoid accidental self-injection.

Observe aseptic precautions.

15. EXPIRY DATE

D.O.M.:
EXP:
Once the vial has been broached the contents should be used within 28 days
Date to be discarded after first broaching:

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.

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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

FOR ANIMAL TREATMENT ONLY

POM-VPS

To be supplied only on veterinary prescription

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

20. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4189 ManA 2000

21. MANUFACTURER'S BATCH NUMBER

B.N:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

Approved: 23/05/2017