

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject LV Solution For Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A clear colourless to pale yellow solution for injection. Each 100 ml contains 4.2 g calcium (provided by calcium gluconate, calcium borogluconate and calcium hydroxide) and 0.78 g magnesium (provided by magnesium chloride hexahydrate). Also contains 7.34% w/v boric acid.

3. PHARMACEUTICAL FORM

Solution For Injection

4. PACKAGE SIZE

Bottles of 100 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Calciject LV is indicated in the treatment of hypocalcaemia complicated by deficiency of magnesium, in cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

CATTLE: 100 - 200 ml

By subcutaneous or slow intravenous injection.

Massage the subcutaneous site gently after administration.

8. WITHDRAWAL PERIOD

Meat/Milk: Zero Days/Hours

9. SPECIAL WARNING(S), IF NECESSARY

Care should be taken to avoid accidental self-injection: may cause irritation at site of injection. Calciject LV does not contain an antimicrobial preservative. Any solution remaining in the vial following withdrawal of the required dose should be discarded.

The solution should be warmed to body temperature before administration. Intravenous injections should be given slowly and stopped on the first signs of adverse reaction. Rapid intravenous injection may result in cardiac arrhythmias and in severely

toxaemic cows, collapse and death. Provided these precautions are observed Calciject LV should be safe for use during pregnancy and lactation.

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

10. EXPIRY DATE

D.O.M.:

Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Protect from light.

Keep container in outer carton.

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

Dispose of empty containers in the farm refuse. Used containers should not be recycled.

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

For animal treatment only.

POM-V To be supplied only on veterinary prescription

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufacturer:

Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Distributed by:

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

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000

Vm 02000/4124

17. MANUFACTURER'S BATCH NUMBER

B.No:

PARTICULARS TO APPEAR ON THE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject LV Solution For Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A clear colourless to pale yellow solution for injection. Each 100 ml contains 4.2 g calcium (provided by calcium gluconate, calcium borogluconate and calcium hydroxide) and 0.78 g magnesium (provided by magnesium chloride hexahydrate). Also contains 7.34% w/v boric acid.

3. PHARMACEUTICAL FORM

Calciject LV Solution

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By subcutaneous or slow intravenous injection.

Massage the subcutaneous site gently after administration.

CATTLE: 100 to 200 ml

8. WITHDRAWAL PERIOD

Withdrawal period for meat/milk – zero days/hours.

9. SPECIAL WARNING(S), IF NECESSARY

The solution should be warmed to body temperature before administration.

Intravenous injections should be given slowly and stopped on the first sign of adverse reaction. Rapid intravenous injections may result in cardiac arrhythmias and in severely toxæmic cows, collapse and death.

Provided these precautions are observed Calciject LV should be safe for use during pregnancy and lactation.

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

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

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

10. EXPIRY DATE

D.O.M.:

B.N.:

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Protect from light.

Keep container in outer carton.

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Co. Down
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BT35 6QQ
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16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000

Vm 02000/4124

17. MANUFACTURER'S BATCH NUMBER

B.No:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

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

Norbrook Laboratories Limited
Newry, Co. Down
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject LV Solution For Injection

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

A clear colourless to pale yellow solution for injection. Each 100 ml contains 4.2 g calcium (provided by calcium gluconate, calcium borogluconate and calcium hydroxide) and 0.78 g magnesium (provided by magnesium chloride hexahydrate). Also contains 7.34% w/v boric acid.

4. INDICATION(S)

Calciject LV is indicated in the treatment of hypocalcaemia complicated by deficiency of magnesium, in cattle.

5. CONTRAINDICATIONS

The solution should be warmed to body temperature before administration. Intravenous injections should be given slowly and stopped on the first signs of adverse reaction. Rapid intravenous injection may result in cardiac arrhythmias and in severely toxæmic cows, collapse and death. Provided these precautions are observed Calciject LV should be safe for use during pregnancy and lactation.

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

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

CATTLE: 100 - 200 ml

9. ADVICE ON CORRECT ADMINISTRATION

By subcutaneous or slow intravenous injection.

Massage the subcutaneous site gently after administration.

10. WITHDRAWAL PERIOD(S)

Meat/Milk: Zero Days/Hours

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Protect from light.

Keep out of the reach and sight of children.

Keep container in outer carton.

12. SPECIAL WARNING(S)

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

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

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

Dispose of empty containers in the farm refuse. Used containers should not be recycled.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

DISTRIBUTED BY:

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

Package Quantities:

Bottles of 100 ml.

BN:

D.O.M:

Exp:

ManA 2000

Vm 02000/4124

POM-VPS – To be supplied only on Veterinary Prescription.

FOR ANIMAL TREATMENT ONLY
UK AUTHORISED VETERINARY MEDICINAL PRODUCT

LOGO

Approved 28 October 2022



Hunter.