

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Megacal – M solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A clear, colourless to pale yellow, sterile solution for injection containing calcium borogluconate and magnesium hypophosphite equivalent to calcium 4.6 g/100 ml, magnesium 0.8 g/100 ml and containing boric acid 10 g/100 ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For treatment of hypocalcaemia and as an aid in raising blood magnesium levels where a deficiency may be expected

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The solution should be warmed to body temperature before use. When administered subcutaneously massage the injection site. Intravenous injections should be carried out slowly and stopped at once if untoward symptoms occur.

Avoid the introduction of contamination during use.

8. WITHDRAWAL PERIOD

Meat/Milk – Zero days/hours

9. SPECIAL WARNING(S), IF NECESSARY

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

Eye Contact: immediately flush the eye with copious amounts of clean running water.

Skin contact: Wash the affected area thoroughly. If irritation occurs seek medical advice.

Ingestion: If accidentally swallowed, seek urgent medical attention and show product label and / or pack insert to the doctor.

ADVICE TO DOCTOR: For treatment advice contact the National Poisons Information Service (NPIS) or your local Poisons Information Centre.

10. EXPIRY DATE

Do not use after stated expiry date

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

11. SPECIAL STORAGE CONDITIONS

Protect from light. Do not store above 25°C

12. SPECIFIC 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.

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

POM-VPS

For animal treatment only

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

KEEP OUT OF REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ballinskelligs Veterinary Products,
Ballinskelligs,
Co. Kerry,
Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 12828/4000

17. MANUFACTURER’S BATCH NUMBER

PACKAGE LEAFLET FOR:

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

Ballinskelligs Veterinary Products,
Ballinskelligs,
Co. Kerry,
Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Megacal-M Solution for Injection

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

A clear, colourless to pale yellow, sterile solution for injection containing calcium borogluconate and magnesium hypophosphite equivalent to calcium 4.6 g/100 ml, magnesium 0.8 g/100 ml and containing boric acid 10 g/100 ml

4. INDICATION(S)

For treatment of hypocalcaemia and as an aid in raising blood magnesium levels where a deficiency may be expected

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

Cattle

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

100 – 200 ml by subcutaneous or SLOW intravenous injection using aseptic technique. Large volumes should be divided between multiple sites.

9. ADVICE ON CORRECT ADMINISTRATION

The solution should be warmed to body temperature before use. When administered subcutaneously massage the injection site. Intravenous injections should be carried out slowly and stopped at once if untoward symptoms occur. In recumbent cows with poor peripheral circulation, administer appropriate calcium therapy intravenously.

Avoid the introduction of contamination during use.

10. WITHDRAWAL PERIOD(S)

Meat/Milk – Zero days/hours

11. SPECIAL STORAGE PRECAUTIONS

Protect from light. Do not store above 25°C

12. SPECIAL WARNING(S)

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

Eye Contact: immediately flush the eye with copious amounts of clean running water.

Skin contact: Wash the affected area thoroughly. If irritation occurs seek medical advice.

Ingestion: If accidentally swallowed, seek urgent medical attention and show product label and / or pack insert to the doctor.

ADVICE TO DOCTOR: For treatment advice contact the National Poisons Information Service (NPIS) or your local Poisons Information Centre. For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION>

POM – VPS To be supplied only on veterinary prescription

Vm 12828/4000

Keep out of reach of children

Do not use after stated expiry date

Approved: 03/01/2018

