SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Megacal-M Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Calcium (as Calcium Gluconate)	4.6g/100ml
Magnesium (as Magnesium Hypophosphite)	0.8g/100ml

Excipient:

Boric Acid	10.0g/100ml

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
A colourless to pale yellow solution

4. CLINICAL PARTICULARS

4.1 Target Species:

Cattle

4.2 Indications for use, specifying the target species

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

4.3 Contra-indications

Known hypersensitivity to the to the active ingredients.
Known cases of cardiac arrhythmia or severe toxaemia

4.4 Special warnings for each target species

The product should be administered with care particularly where concurrent toxaemia exists. In recumbent cows with poor peripheral circulation, administer appropriate calcium therapy intravenously.

4.5 Special precautions for use

Warm the product to body temperature before administration.
When the intravenous route is being used, extreme caution must be taken to ensure slow administration.
This product does not contain an antimicrobial preservative. Any solution remaining in the vial after withdrawal of the required dose should be discarded.

Special precautions to be taken by the person administering the product to animals

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.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Safe for use during pregnancy and lactation

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

By subcutaneous or slow intravenous injection.
Cattle – 100 - 200ml.
Large volumes should be divided between multiple sites. Massage sites gently.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The product is for treatment of acute deficiency in a life threatening situation and overdosage within the recommended guidelines is unlikely.

4.11 Withdrawal period(s)

Meat – Zero days
Milk – Zero hours

5. PHARMACOLOGICAL PROPERTIES

This product is intended to restore blood calcium levels in cases of hypocalcaemia.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Boric Acid
Water for Injection
Sodium Hydroxide (For pH adjustment)
Acetic Acid (For pH adjustment)

6.2 Major incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale**:**
3 years.

6.4 Special precautions for storage

Store below 25˚C. Protect from light.

6.5 Nature and composition of immediate packaging

A 100ml clear glass vial with nitryl rubber bung and gold seal containing a clear, colourless to pale yellow sterile solution

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 12828/4000

9. DATE OF FIRST AUTHORISATION

01 February 1999

10. DATE OF REVISION OF THE TEXT

January 2015

Approved: 29 January 2015