1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Megacal-M 46 mg/ml + 20 mg/ml + 8 mg/ml solution for injection for cattle

2 . QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Calcium 46 mg
(As calcium borogluconate)

Phosphorous 20 mg
(As magnesium hypophosphite)

Magnesium 8 mg
(As magnesium hypophosphite)

Excipients:

Qualitative composition of excipients and other constituents
Water for Injection

A clear, colourless to pale yellow sterile solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the treatment of the following conditions when complicated by phosphorus and magnesium deficiency:

- Paresis caused by hypocalcaemia before, during or after calving or during lactation.
- Downer cow syndrome (including during pregnancy) caused by deficiency diseases or internal secretory dysfunction.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The solution should be warmed to body temperature before use. Administer with care particularly where concurrent toxaemia exists. Intravenous administration should be carried out slowly and stopped at once if untoward symptoms occur.
As intravenous administration of this product could cause death, this route should only be used by a veterinary practitioner.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle

Undetermined frequency (cannot be estimated from the available data):	Cardiotoxic effects[1]

[1]if administered too rapidly or overdosed.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Subcutaneous or slow intravenous use.

Actual dosage to be given intravenously will depend upon the clinical condition of the animal and the amount to use is left to the discretion of the veterinary practitioner.
The recommended dose rate is: 100 –200 ml.

Any product remaining in the vial following withdrawal of the required dose should be discarded.

When administered subcutaneously massage the injection site.

3.10 Symptoms of overdose (and where applicable, emergency procedures, antidotes

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero Days.

Milk: Zero Hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QA12AA

4.2 Pharmacodynamics

For restoration of normal calcium levels in cases of clinical hypocalcaemia and as an aid in raising blood magnesium and phosphorus levels, in the event of a concurrent deficiency.

5 PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25ºC.
Protect from light.

5.4 Nature and composition of immediate packaging

A 100 ml clear glass vial with nitryl rubber bung and gold coloured aluminium seal.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such product

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6 NAME OF THE MARKETING AUTHORISATION HOLDER

Tairgi Tread-Lia Baile na Sceilge Teo,
(Ballinskelligs Veterinary Products)

7 MARKETING AUTHORISATION NUMBER(S)

VPA10956/001/001

8 DATE OF THE FIRST AUTHORISATION

01/10/1991

9 DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

20/08/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).