Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Megacal-M Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances

Calcium	4.6 % w/v
As Calcium Borogluconate	
Phosphorous	2.0 % w/v
As magnesium hypophosphite	
Magnesium	0.8 % w/v
As magnesium hypophosphite	

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless to pale yellow sterile solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For the treatment of the following conditions when complicated by Phosphorus and Magnesium deficiency:-
Paresis caused by hypocalcemia before, during or after calving or during lactation.
Downer cow syndrome (including during pregnancy) caused by deficiency diseases or internal secretory dysfunction.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
The solution should be warmed to body temperature before use. 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.
When administered subcutaneously massage the injection site.

Special precautions to be taken by the person administering the product to animals
None.

4.6 Adverse reactions (frequency and seriousness)

Cardiotoxic effects, if administered too rapidly or overdosed.

4.7 Use during pregnancy, lactation or lay

This product may be used 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

Administration is by subcutaneous or slow intravenous injection.
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

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 or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QA12AA

Pharmacotherapeutic Group: Mineral supplements, calcium

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injection

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Any product remaining in the vial following withdrawal of the required dose should be discarded.

6.4 Special precautions for storage

Protect from light.
Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

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

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Tairgi Tread-Lia Baile na Sceilge Teo,
(Ballinskelligs Veterinary Products),
Ballinskelligs,
Killarney,
Co. Kerry,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10956/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2006

10 DATE OF REVISION OF THE TEXT

19th July 2010