

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

B.V.P. Calcium 40 Plus Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Calcium 3.00 % w/v
(as calcium borogluconate)

Phosphorous 0.70 % w/v
(as magnesium hypophosphite)

Magnesium 0.28 % w/v
(as magnesium hypophosphite)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A solution for injection.

A clear colourless to pale yellow sterile aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For treatment of hypocalcaemia when complicated by Magnesium and Phosphorus deficiency.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

The product should be administered with care particularly where concurrent toxaemia exists.

4.5 Special precautions for use

Special precautions for use in animals

Warm the product to body temperature before use.

When administered subcutaneously, massage the injection site.

When administered intravenously, extreme caution must be taken to ensure slow administration. As intravenous administration of the product could cause death, this route should only be used by a veterinary practitioner. Cardiac function should be evaluated during and immediately after administration by this route. Intravenous administration should be stopped at once if untoward symptoms occur.

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

None.

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

Administration is by subcutaneous or slow intravenous injection.

The actual dose to be given intravenously will depend on the clinical condition of the animal, and the amount to use intravenously is left to the discretion of the veterinary practitioner.

The recommended dosage rate is: up to 400ml.

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: Nil.

Milk: Nil.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The product is designed for treatment of hypocalcaemia when complicated by Magnesium and Phosphorus deficiency.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Any product remaining after the date of first broaching the seal shall be discarded.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

A 400 ml polypropylene bottle with a grey bromobutyl bung, polypropylene screw cap and tamper evident 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,
Co. Kerry.
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10956/003/003

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2006

10 DATE OF REVISION OF THE TEXT

24th March 2011