1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject 40 Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances

Calcium borogluconate 400.0 mg/ml (Equivalent to calcium gluconate 29.6 mg/ml) (Equivalent to calcium 29.6 mg/ml) Boric Acid 68.0 mg/ml

3 PHARMACEUTICAL FORM

Solution for injection.

A clear pale yellow sterile aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Calciject 40 is indicated in the treatment of hypocalcaemia.

4.3 Contraindications

None.

4.4 Special warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precautions for use in animals

The solution should be warmed to body temperature before administration. Intravenous injections should be given slowly and stopped at the first signs of adverse reaction. Rapid intravenous injection may result in cardiac arrhythmias and in severely toxaemic animals collapse and death. As intravenous administration of this product could cause death, this route should only be used by a veterinary surgeon.

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

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

Calciject 40 can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

No known interactions.

4.9 Amounts to be administered and administration route

Administer by subcutaneous or slow intravenous injection.

Cattle: 150 - 400 ml

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

Not applicable.

4.11Withdrawal Period(s)

Meat: Nil Milk: Nil

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Milk fever which is characterised by hypocalcaemia is caused by an acute drop in the level of ionised calcium.

Administration of calcium borogluconate by subcutaneous or slow intravenous injection replenishes plasma calcium levels and reverses the hypocalcaemia.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Bicarbonate Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of veterinary medicinal product as packaged for sale: 2 years For single use only. Any unused material should be discarded after opening.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

400 ml polypropylene containers with bromobutyl bungs (grey) and aluminium caps.

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

Norbrook Laboratories (Ireland) Limited

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/031/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/10/1991

10 DATE OF REVISION OF THE TEXT

25/03/2024