1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calcivet Solution for Injection for Cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Calcium Gluconate	332 mg
Boric Acid	68 mg
Magnesium hypophosphite hexahydrate	30 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium hydrogen carbonate
Water for Injection

A clear pale yellow aqueous solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated in the treatment of hypocalcaemia complicated by deficiency of magnesium.

3.3 Contraindications

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

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 administration. Intravenous injections should be given slowly and stopped on 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 veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment

Not applicable.

3.6 Adverse events

None known.

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 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

Pregnancy and lactation:

The veterinary medicinal product can be safely administered to pregnant and lactating animals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Administer by subcutaneous or slow intravenous injection.

Cattle: 150 - 400 ml

The product is for single use only.

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

Not applicable.

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: QA12A

4.2 Pharmacodynamics

Milk fever characterised by hypocalcaemia is caused by an acute drop in the level of calcium in the blood. At parturition hypophosphataemia and hypomagnesaemia can also occur. The veterinary medicinal product administered by subcutaneous or slow intravenous injection replenishes plasma concentration of calcium, phosphate and magnesium ions.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Do not store above 25°C.

Protect from light.

5.4 Nature and composition of immediate packaging

The product is marketed in 400 ml amber Type II glass vials sealed with rubber wads and aluminium screw caps or 400ml polypropylene containers sealed with bromobutyl bungs (grey) and aluminium caps.

Not all pack sizes may be marketed.

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

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

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/054/001

8. DATE OF FIRST AUTHORISATION

02/10/2000

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

12/06/2024

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).