

Summary of Product Characteristics

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:

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

A clear pale yellow aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Calcivet is indicated in the treatment of hypocalcaemia complicated by deficiency of magnesium.

4.3 Contraindications

None.

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 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 toxæmic animals collapse and death.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Calcivet can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

None.

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.

4.11 Withdrawal period(s)

Meat and offal: zero days

Milk: zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Alimentary tract and metabolism, mineral supplements; calcium

ATC vet code: QA12A

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. Calcivet administered by subcutaneous or slow intravenous injection replenishes plasma concentration of calcium, phosphate and magnesium ions.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Hydrogen Carbonate
Water for Injection

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years. The product is for single-use only.

6.4 Special precautions for storage

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

6.5 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.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/054/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02 October 2000
Date of last renewal: 01 October 2010

10 DATE OF REVISION OF THE TEXT

January 2019