

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Calcitat 25, solution for infusion and injection in cattle.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml of solution contains:

#### Active Substances

Calcium gluconate monohydrate	1.55 g
Calcium borogluconate	21.45 g
Calcium hydroxide	0.66 g
Magnesium Chloride hexahydrate	3.25 g

#### Excipients

Methyl Parahydroxybenzoate (E219) 0.10 g

For a full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Solution for infusion and injection.

A clear colourless solution.

### 4 CLINICAL PARTICULARS

#### 4.1 Target Species

Bovine.

#### 4.2 Indications for use, specifying the target species

Paresis resulting from hypocalcaemia before, during and after parturition or during lactation. Downer cow syndrome.

#### 4.3 Contraindications

Do not use in case of hypersensitivity to the active substances.

Do not use in animals suffering from hypercalcaemia, hyperparathyroidism, acidosis, severe kidney damage.

#### 4.4 Special warnings for each target species

Caution must be exercised when this product is used intravenously. As intravenous administration of this product could cause death, this route should only be used by a veterinary surgeon.

## **4.5 Special precautions for use**

### **Special precautions for use in animals**

Intravenous - administer slowly and at body temperature. Monitor cardiac performance during administration.  
Subcutaneous - divide large volumes into several injection sites.

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

None.

## **4.6 Adverse reactions (frequency and seriousness)**

Rapid intravenous infusion may result in transient cardiac distress.

## **4.7 Use during pregnancy, lactation or lay**

The product may safely be used during pregnancy and lactation and most clinical indications occur at this time.

## **4.8 Interaction with other medicinal products and other forms of interaction**

The use of admixtures should be avoided because of possible incompatibility with other substances in solution.

## **4.9 Amounts to be administered and administration route**

Administer by intravenous or subcutaneous injection.

Dosage: Cattle: 400-440ml / 500 kg body weight

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

Symptoms of overdose would be cyanosis, dyspnoea, prostration, terminal excitement and ventricular fibrillation.

## **4.11 Withdrawal Period(s)**

Meat and offal: zero days.

Milk: zero days.

## **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group and ATC vet code:

Alimentary tract and metabolism, mineral supplements, calcium gluconate. QA12AA03.

Alimentary tract and metabolism, mineral supplements, magnesium chloride. QA12CC01.

Replacement therapy to supply calcium as a corrective for hypocalcaemia for the treatment of milk fever, parturient paresis and similar conditions. Calcitat 25 is a complex of calcium-magnesium-gluconic acid and boric acid, supplemented with phosphorylethanolamine stimulating metabolism.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

2-Aminoethyl dihydrogen phosphate

Methyl Parahydroxybenzoate (E219)

Macrogol 200

Water for Injections

### **6.2 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: 3 years

Shelf-life after first opening the immediate packaging: 28 days.

### **6.4 Special precautions for storage**

Do not store above 25°C.

Do not store below 8°C.

### **6.5 Nature and composition of immediate packaging**

250 ml and 500 ml

Vial: Sterile plastic bottles (Type PP28)

Stopper: Chlorobutyl rubber stopper

Cap: Aluminium cap

Not all pack sizes may be marketed.

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

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

## **7 MARKETING AUTHORISATION HOLDER**

AniMedica GmbH

Im Südfeld 9

48308 Senden-Bösensell

Germany

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10826/001/001

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

30<sup>th</sup> September 2009

**10 DATE OF REVISION OF THE TEXT**