SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Infucal vet., solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Each ml contains:
Calcium gluconate .....175.0 mg
Magnesium chloride.....21.9 mg
(as magnesium chloride hexahydrate)

Excipients:

Each ml contains:
Glucose monohydrate .....110.0 mg
Sodium hypophosphite.....40.5 mg
Boric acid (E-284) .....35.8 mg
Water for injections to .....1.0 ml

3. PHARMACEUTICAL FORM

Solution for infusion.
Clear slightly yellowish solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

Paresis puerperalis and other conditions with hypocalcemia in cattle. The magnesium of the veterinary medicinal product is beneficial in hypomagnesemia.

4.3 Contraindications

Do not use in hyperexcited animals.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The solution shall have reached body temperature before administration in large quantities.
Do not administer to hyperexcited animals.
If tachypnea, tachycardia or bradycardia occurs, the infusion shall be interrupted until the cardiac rhythm is normalized.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Intravenous administration can cause phlebitis and/or clotting at infusion site. To avoid this problem, the infusion should be administered slowly through an intravenous catheter.
Bradycardia and cardiac arrhythmia might appear if the intravenous infusion is given too fast. The infusion shall then be interrupted until normalization of cardiac rhythm. Bradycardia and cardiac arrhythmia should be controlled before and during treatment.

4.7 Use during pregnancy or lactation

Pregnancy:
Can be used during pregnancy.

Lactation:
Can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer with tetracyclines, sodium carbonate, streptomycin or dihydrostreptomicin sulphate. Calcium gluconate increases the activity of methylxanthines on the heart.

4.9 Amounts to be administered and administration route

By slow intravenous infusion. General dosage is 1 ml per kg bodyweight (15.6 mg calcium and 2.6 mg magnesium per kg b.w.) given consideration to the clinical status of the animal.

In hypomagnesemic conditions additional magnesium may have to be administered intravenously or subcutaneously according to the clinical status of the animal.

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

High doses during longer periods can cause nausea, muscle weakness, bradycardia, tachycardia and arrhythmia.

4.11 Withdrawal period

Zero days.

5. PHARMACOLOGICAL PROPERTIES

Calcium gluconate with Magnesium chloride
Pharmacotherapeutic group: mineral supplements
ATCvet code: QA12AX

5.1 Pharmacodynamic properties

Calcium (gluconate):
Calcium has a large number of essential functions in the organism, such as its role in bone tissue metabolism, in muscular contraction and in the transmission of nerve impulses and in blood clotting.

Magnesium:
Magnesium is, in quantity, the second most abundant intracellular essential cation in the organism. It acts as a co-factor in enzymatic systems and takes part in phosphate transport, muscular contraction and nerve impulse transmission.

5.2 Pharmacokinetic particulars

Calcium (gluconate):
Calcium is a mineral that represents 2% of a ruminant's body weight. It is mainly stored in bone tissue and in teeth (90%). Only 1% of calcium is in body liquids. Calcium is in plasma as a non-interchangeable protein complex, as an interchangeable complex with dissociate ions, such as citrate, bicarbonate or phosphate or as Ca^{++}. Calcium concentration in plasma is between 8 – 12 mg/100 ml.
Bone tissue is the body's calcium reserve.
Calcium is excreted through the urine, faeces, milk and genitals.

Magnesium:
The distribution of magnesium in the body of animals is similar to that of phosphorus. Approximately 70% of body magnesium is found in bone tissue. The remaining 30% is distributed in body liquids.
Magnesium concentration in serum is between 2 – 3.5 mg/100 ml.
There is more magnesium than calcium in muscle, which is the opposite of blood in which there is a lower, but constant, amount of magnesium.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose monohydrate
Sodium hypophosphite
Boric acid (E-284)
Water for injections

6.2 Incompatibilities

Do not mix the veterinary medicinal product with other medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
The veterinary medicinal product should be used immediately and not stored after opening.

6.4. Special precautions for storage

Do not store above 25 °C. Keep the container in the outer carton. Do not freeze.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is presented in 500 ml polyethylene bottles. In the bottom a ring is attached to facilitate a hang up of the bottle, in the case of slow infusion.
Packages sizes: 1 x 500 ml and 12 x 500 ml.
Not all pack sizes may be marketed.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Nordvacc Läkemedel AB
Västertorpsvägen 135
Box 112
S-129 22 Hägersten
Sweden

8. MARKETING AUTHORISATION NUMBER

13900

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1999-01-28/2009-01-23

10. DATE OF REVISION OF THE TEXT

2019-05-02

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.