PACKAGE LEAFLET

Infucal vet., solution for infusion

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Nordvacc Läkemedel AB
Västertorpsvägen 135
Box 112
S-129 22 Hägersten
Sweden

Manufacturer responsible for batch release:
Divasa-Farmavic S.A.
Ctra. Sant Hipolit, km 71,
08503-Gurb-Vic, Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Infucal vet., solution for infusion

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each ml contains :

Active substances:
Calcium gluconate……...175.0 mg
Magnesium chloride……..21.9 mg
(as magnesium chloride hexahydrate)

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

4. INDICATIONS

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

5. CONTRAINDICATIONS

Do not use in hyperexcited animals.

6. ADVERSE REACTIONS

Intravenous administration can cause phlebitis and/or clotting at infusion site. To avoid this problem, the infusion should be administered 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. These two symptoms should be controlled before and during treatment.

If you notice any side effects, even those not already listed in this package leaflet or you think that medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system national system details.

7. TARGET SPECIES

Cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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

9. ADVICE ON CORRECT ADMINISTRATION

- The solution shall have reached body temperature before administration in large quantities.
- If tachypnea, tachycardia or bradycardia occurs, the infusion shall be interrupted until the cardiac rhythm is normalized.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C. Keep the container in the outer carton. Do not freeze.
This veterinary medicinal product should be used immediately and not stored after opening.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Overdose (symptoms, emergency procedures, antidotes):
High doses during longer periods can cause nausea, muscle weakness, bradycardia, tachycardia and arrhythmia.

Interaction with other medicinal products and other forms of interaction:
Do not administer the product with tetracyclines, sodium carbonate, streptomycin sulphate or dihydrostreptomicin sulphate. Calcium gluconate increase the activity of methylxanthines on the heart.

Pregnancy and lactation:
It can be used during pregnancy and lactation.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

2019-05-02.

15. OTHER INFORMATION

Presentation: 1x 500 ml and 12 x 500 ml. To facilitate the hang up of the bottle, a ring is attached in the bottom.

Not all pack sizes may be marketed.

For animal treatment only.