

Package leaflet

NICALCIMAG solutio pro injectionibus

NICALCIMAG solution for injection

Solution for injection intended for horses, foals, cattle, calves, sheep, goats, lambs, kids, swine, pigs, dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURER IF THEY ARE DIFFERENT

VETPROM AD, Bulgaria,
2400 Radomir, 26 Otets Paisii Str
Tel.: 0777/8-24-93, 8-02-68; fax: 0777/8-23-91
E-mail: vetprom@abv.bg

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NICALCIMAG solution for injection
NICALCIMAG solutio pro injectionibus

3. ACTIVE SUBSTANCE AND EXCIPIENT CONTENT

Active substances:

Calcium Borogluconate	100 mg/1 ml
Magnesium gluconate	60 mg/1 ml
Calcium Glicerophosphate	50 mg/1 ml
Glucose	50 mg/1 ml

Excipients:

Chlorocresol, Water for injections

4. THERAPEUTIC INDICATIONS

In medical conditions associated with deficiency of calcium, magnesium and phosphorus: rachitis, osteomalacia, fluid retention before and after birth, postpartum paresis, grass tetany, dairy and transport tetany and acidosis, in case of hemorrhagic diathesis, intoxications with chlorinated carbohydrates, fluor and lead compounds.

5. CONTRAINDICATIONS

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

Do not use in case of hypercalcaemia and tendency to thrombosis.

Do not use in case of impaired hepatic and renal function.

6. ADVERSE REACTIONS

If during injection a visceral or cardiac syndrome occurs (sweating, shivering, heart rhythm disorders), injection speed should be reduced or product administration should be discontinued.

The frequency of the adverse reactions is determined by the following classification:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 out of 100 animals)
- uncommon (more than 1 but less than 10 out of 1,000 animals)
- rare (more than 1 but less than 10 out of 10,000 animals)
- very rare (less than 1 out of 10,000 animals including isolated reports).

If you notice any serious or other side effect caused by the use of this veterinary medicinal product not listed in this leaflet, please inform immediately your veterinarian.

7. ANIMAL SPECIES FOR WHICH THIS VETERINARY MEDICINE IS INTENDED

Horses, foals, cattle, calves, sheep, goats, lambs, kids, swine, pigs, dogs and cats.

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

Dose:

Horses and cattle 100-200 ml;

Foals and calves 100 ml;

Sheep, goats and swine 25-30 ml;

Lambs, kids and pigs 5-10 ml;

Dogs and cats 2-10 ml.

Repeated treatment in 24 hours.

Method of administration:

-Intramuscular and subcutaneous; if the solution is in greater amounts, it should be divided into several injection sites.

-Intravenous (slowly).

This product contains no antimicrobial agents, and the contents should be for a single use. Prior to use, both vials and contents should be warmed to body temperature.

9. INSTRUCTIONS FOR PROPER ADMINISTRATION

Always use NICALCIMAG solution for injection as your veterinarian has told you., Check with your veterinarian if you are not sure.

10. WITHDRAWAL PERIOD

Meat and internal organs: 0 (zero) days.

Milk: 0 (zero) days.

11. SPECIAL REQUIREMENTS FOR STORAGE

Keep out of the sight and reach of children.

Store below 25 °C

Protect from light.

Store in dry places.

Do not use this veterinary medicine after the expiry date which is stated on the label.

Shelf life after first opening : 28 days. Store in a refrigerator (2 °C – 8 °C).

12. SPECIAL WARNINGS

Special precautions for the animals during the product use

Handle the product under aseptic conditions because it contains no antimicrobial agents, and is a rich nutritional medium for bacteria.

Prior to use, glass and its contents should be tempered to body temperature.

If a visceral or heart syndrome occurs, reduce the injection speed or discontinue it.

Interaction with other veterinary medicinal products or other forms of interaction:

When handling calcium-containing products, syringes or infusion sets should not contain alcohol. Calcium ion crystallizes. Combine with vitamin products, particularly Vitamin D – Hydro AD₃E in oral dose of 0.5 to 2 ml per animal. Avoid strofantin products.

Overdosage (symptoms, emergency measures, antidotes) if required

In case of rapid intravenous infusion, and if the solution is not warmed to body temperature, heart rhythm disorders and sweating of the animal may occur. It is a result of the fast saturation of blood with calcium ions.

Overdose measures

If such a clinical picture should appear, injection speed should be reduced or the infusion discontinued.

13. SPECIAL PRECAUTIONS FOR DISPOSAL OF ANY UNUSED PRODUCT OR WASTE MATERIAL

Do not throw away any veterinary medicines via wastewater or household waste. Ask your veterinarian how to throw away veterinary medicines you no longer use. These measures will help protect the environment.

14. DATE OF LATEST REVISION OF THE TEXT

24/02/2015

15. FURTHER INFORMATION

For any information in relation to this veterinary medicinal product, please contact the local representative of the marketing authorization holder.

VETPROM AD

2400 Radomir, Bulgaria, 26 Otets Paisii Str

Tel: 0777/8-24-93, 8-00-19

FAX: 0777/8-23-91

E-mail: vetprom@abv.bg