SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Phosphorus Supplement 1.8 % w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Qualitative composition	Quantitative composition
Calcium hypophosphite (equivalent to Phosphorus 1.8 % w/v)	4.84 % w/v

Excipients

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless, sterile, aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

For the treatment of acute hypophosphataemia in cattle. Also as an aid in raising blood calcium levels where a deficiency may be expected.

4.3 Contraindications

Do not use in hyperphosphataemic animals.

4.4 Special warnings for each target species

Preferably warm the solution to body temperature before use.

4.5 Special precautions for use

i. Special precautions for use in animals

None known.

ii. Special precautions for the person administering the veterinary medicinal product to animals

If contact with the skin occurs, the area should be washed with soap and water. If irritation occurs, seek medical advice.
If contact with eyes occurs, wash eyes with plenty of clean water. If irritation occurs, seek medical advice.
Following oral ingestion, the mouth should be washed out and plenty of water consumed. Seek medical advice if irritation occurs.
If accidental self-injection occurs or if signs of adverse effects are seen, seek medical attention immediately, showing the product label to a doctor.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not contraindicated.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

Cattle: up to 400 ml by intravenous injection (approximately 1 ml/kg/day).

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

Do not exceed stated dose.

4.11 Withdrawal periods

Meat: zero days.
Milk: zero hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Mineral supplements, Other mineral supplements, Other mineral products.

ATC Vet Code:

QA12CX

5.1 Pharmacodynamic properties

Hypophosphataemia is a nutritional disorder affecting cattle. It is characterised by a decrease in the plasma phosphorus concentration to below the normal range. The condition is often associated with deficiencies in calcium and magnesium such as post-parturient paresis, lactation tetany and grass tetany.
Phosphorus, in the form of phosphates, is the principle anion of intracellular fluid. Phosphorus and calcium are intricately involved in bone growth and calcification. Phosphate is mainly used in metabolism of carbohydrates and lipids, the storage and transfer of energy in cells occurring in nucleic acids, the formation of the body buffering system which influences acid-base balance, and in the renal excretion of hydrogen ions in the urine.
Where there is a soil phosphate deficiency, animals require supplementation to prevent the appearance of chronic deficiency (characterised by anorexia and pica, impaired weight gain, infertility and lameness).
Commercial preparations, usually containing calcium and phosphorus as the hypophosphite, are used. Up to 100 mmol per day may be given by slow intravenous injection in cases of severe hypophosphataemia. Plasma electrolyte concentrations, especially phosphate and calcium should be monitored. In excess, the more soluble phosphates have a laxative effect which is counter-productive.
Injections can be given intravenously, using normal aseptic techniques.
Excessive administration of phosphate may cause hyperphosphataemia.

5.2 Pharmacokinetic properties

The metabolism of cyanocobalamin is complex and is associated closely with that of folic acid and of ascorbic acid. It is important for maintenance of normal haemopoiesis, protection of the liver, maintenance of muscle tissue, healthy skin, brain and pancreatic metabolism.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.
This product does not contain an antimicrobial preservative. Any remaining

solution in the bottle following withdrawal of the required dose should be discarded.

6.5 Nature and composition of immediate packaging

400 ml type II amber glass bottle, fitted with a grey rubber stopper and push off polypropylene cap.

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

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

7. MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 36408/4010

9. DATE OF FIRST AUTHORISATION

06 July 1995

10. DATE OF REVISION OF THE TEXT

August 2021

Approved: 18/08/21