Revised: August 2021 AN: 00888/2021

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

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

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Dales Pharmaceuticals Ltd Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Phosphorous supplement 1.8% w/v solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Contains:

Active substances: Calcium hypophosphite 48.04% w/v (Equivalent to phosphorous 1.8% w/v)

4. PHARMACEUTICAL FORM

Solution for injection.

5. PACKAGE SIZE

400 ml

6. INDICATION

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

7. CONTRAINDICATIONS

Do not use in hyperphosphataemic animals.

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9. TARGET SPECIES

Cattle.

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage and Administration

Up to 400 ml by intravenous injection (approximately 1 ml/kg/day).

11. ADVICE ON CORRECT ADMINISTRATION

Warm the solution to body temperature before use. Observe aseptic precautions.

12. WITHDRAWAL PERIOD

Meat: Zero days; Milk: Zero hours

13. SPECIAL STORAGE PRECAUTIONS

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.

14. SPECIAL WARNING(S)

Special warnings for each target species:

In herds with a history of hypophosphataemia, dietary supplements with phosphorus may be required.

User warnings:

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 reactions are seen, seek medical attention immediately, showing the product label to a doctor.

Wash hands after use.

15. EXPIRY DATE

EXP: month/year

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16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on a veterinary prescription.

POM-V

Prescription Only Medicine – Veterinarian

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

20. MARKETING AUTHORISATION NUMBER(S)

Vm 36408/4010

21. MANUFACTURER'S BATCH NUMBER

Lot: {number}

22. OTHER INFORMATION

UK authorised veterinary medicinal product.

Local representative:

Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom.

Approved: 18/08/21

D. Austur