

PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitbee 250

0.025 % w/v solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Containing:

Cyanocobalamin (vitamin B12) 0.025 % w/v

Phenol 0.5 % w/v (as a preservative)

3. PHARMACEUTICAL FORM

A clear red, sterile solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Sheep, foals and calves

6. INDICATION(S)

An aid in raising blood vitamin B12 levels in foals, calves and sheep.

For use in the treatment of vitamin B12 deficiency, and for poor growth rates and general unthriftiness in young animals when associated with the above deficiency.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: Sheep 1-3 ml

Calves and foals 2-4 ml

For intramuscular or subcutaneous injection.

Repeat in 7 days in required.

Following treatment, the vitamin B12 status of herbivores should be maintained by dietary supplementation with cobalt.

8. WITHDRAWAL PERIOD

Meat: Zero days;

Milk: Zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

For animal treatment only.
Do not give by the intravenous route.
Observe normal aseptic precautions.

User Warnings

Care should be taken to avoid accidental self-injection or ingestion. In the case of accidental self-injection or ingestion, seek medical advice as a precautionary measure. Following skin/eye contamination, wash/irrigate area thoroughly with cold water.

Seek medical attention if irritation persists.
Wash hands after use.

10. EXPIRY DATE

EXP:

Following withdrawal of the first dose, use the product within 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Protect from light.

Keep out of the sight and reach of children.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of empty packaging and any remaining product in the farm or stable refuse.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS

16. MARKETING AUTHORISATION NUMBER

Vm 36408/4011

17. MANUFACTURER’S BATCH NUMBER

Lot: {number}

18. OTHER INFORMATION

To be supplied only on veterinary prescription.

UK authorised veterinary medicinal product.

Local representative:

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

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

Vitbee 250

0.025 % w/v solution for injection

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

Containing:

Cyanocobalamin (vitamin B12) 0.025 % w/v;

Phenol 0.5 % w/v (as a preservative).

4. PHARMACEUTICAL FORM

A clear, red, sterile solution for injection

5. PACKAGE SIZE

50 ml

6. INDICATION(S)

An aid in raising blood vitamin B12 levels in foals, calves and sheep.

For use in the treatment of vitamin B12 deficiency, and for poor growth rates and general unthriftiness in young animals when associated with the above deficiency.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Sheep, foals and calves

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

Dosage: Sheep 1-3 ml; Calves and foals 2-4 ml.

For intramuscular or subcutaneous injection. Repeat in 7 days if required.

11. ADVICE ON CORRECT ADMINISTRATION

Do not give by the intravenous route.

Observe normal aseptic precautions.

Following treatment, the vitamin B12 status of herbivores should be maintained by dietary supplementation with cobalt.

12. WITHDRAWAL PERIODS

Meat: Zero days; Milk: Zero hours.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Protect from light.

Keep the container in the outer carton.

14. SPECIAL WARNING(S)

User Warnings

Care should be taken to avoid accidental self-injection or ingestion.

In the case of accidental self-injection or ingestion, seek medical advice as a precautionary measure.

Following skin/eye contamination, wash/irrigate area thoroughly with cold water.

Seek medical attention if irritation persists.

Wash hands after use.

15. EXPIRY DATE

Exp: month/year

Following withdrawal of the first dose, use the product within 28 days.

Once broached use by: _/_/_

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

Dispose of empty containers and any remaining product in the farm refuse or stable refuse.

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

POM-VPS

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

Vm 36408/4011

21. MANUFACTURER’S BATCH NUMBER

Lot:

22. OTHER INFORMATION

For animal treatment only.

To be supplied only on veterinary prescription.

Approved: 18/08/21

