

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE – Label and base label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anivit B12 Solution for Injection 250 µg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Cyancobalamin (Vitamin B12) 250 micrograms in 1 ml.

Phenol 0.5% w/v (as preservative).

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Sheep, calves, foals.

6. INDICATION(S)

Uses: For intramuscular or subcutaneous injection. As an aid in raising blood Vitamin B12 levels in sheep, calves and foals. 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.

Foals and calves: 2-4 ml

Repeat in 7 days if required.

8. WITHDRAWAL PERIOD

Cattle, sheep, horse meat: Zero days

Cattle, sheep milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Do not give by the intravenous route.

Observe normal aseptic precautions.

10. EXPIRY DATE

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

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

Do not store above 25°C.

Protect from light.

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

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

For animal treatment only.

POM-VPS

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and site of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

16. MARKETING AUTHORISATION NUMBER

Vm 10434/4067

17. MANUFACTURER’S BATCH NUMBER

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

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Anivit B12 Solution for Injection 250 µg/ml

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

A clear, red, sterile solution for injection containing Cyanocobalamin (Vitamin B12) 250 micrograms in 1 ml.

The product contains Phenol 0.5% w/v as a preservative.

4. PHARMACEUTICAL FORM

Solution for injection.

5. PACKAGE SIZE

50 ml

6. INDICATION(S)

Uses: As an aid in raising blood Vitamin B12 levels in sheep, calves and foals. 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

Do not give by the intravenous route.

8. ADVERSE REACTIONS

9. TARGET SPECIES

Sheep, calves and foals.

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

Sheep: 1-3 ml

Foals and calves: 2-4 ml

By 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.

12. WITHDRAWAL PERIOD

Cattle, sheep and horse meat: Zero days.

Cattle and sheep milk: Zero hours.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Protect from light.

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

14. SPECIAL WARNING(S)

Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical advice immediately.

In case of accidental ingestion, seek medical advice immediately.

In case of accidental spillage onto the skin or eyes, wash the affected area immediately with clean running water.

Seek medical advice if irritation persists.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

15. EXPIRY DATE

When the container is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out.

The discard date should be written in the space provided on the label.

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

Rinse containers thoroughly with water. Dispose of rinsings in slurry or dirty water. Dispose of rinsed containers in the farm refuse. Used containers should not be recycled.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

January 2014

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

For animal treatment only.

POM-VPS

Prescription Only Medicine – Veterinarian, Pharmacist, Suitably Qualified Person

To be supplied only on veterinary prescription.

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and site of children.

20. MARKETING AUTHORISATION NUMBER

Vm 10434/4067

21. MANUFACTURER’S BATCH NUMBER

22. OTHER INFORMATION

UK authorised veterinary medicinal product.

Package quantity: Multidose vial of 50 ml

Further information: Following treatment, the Vitamin B12 status of herbivores should be maintained by dietary supplementation with Cobalt.

Animalcare Ltd, 19 Great North Way, York, YO26 6RB, UK.

Approved: 27/06/2017

