

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Anivit B12 Solution for Injection 250 µg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredient</u>	<u>% w/v</u>
Cyanocobalamin	0.025

<u>Other ingredients</u>	
Phenol (Preservative)	0.500

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

A clear, red, sterile solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep, foals and calves.

4.2 Indications for use, specifying the target species

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

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.

4.3 Contra-indications

Do not give by the intravenous route.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

i. Special precautions for use in animals

Take adequate measures to maintain sterility.
Observe normal aseptic precautions.

- ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

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 spillage onto the skin or eyes, wash the affected area immediately with clean running water. Seek medical attention if irritation persists.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not contra-indicated in pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Sheep 1-3 ml
Foals and calves 2-4 ml

By intra-muscular or subcutaneous injection.

Repeat in 7 days if required.

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

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

Overdosage is unlikely.

4.11 Withdrawal periods

Cattle – Meat: Zero days
Milk: Zero hours

Sheep –Meat: Zero days
Milk: Zero hours

Horses –Meat: Zero days

5. PHARMACOLOGICAL PARTICULARS

Pharmacotherapeutic group: Cyanocobalamin
ATC Vet Code: QB03BA01

5.1 Pharmacodynamic properties

B vitamins are not stored in the body to any great extent.

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

Phenol
Sodium acid phosphate dihydrate
Sodium chloride
Water for injections

6.2 Incompatibilities

None.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and contents of immediate packaging

Amber glass vial fitted with a red pharmaceutical grade rubber multidose plug and an aluminium seal, containing 50 ml sterile injection for parenteral administration.

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

Dechra Limited
Staffordshire

8. MARKETING AUTHORISATION NUMBER

Vm 10434/4067

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27/10/1999
Date of renewal of the authorisation: 27/10/2004

10. DATE OF ANY REVISION OF THE TEXT

February 2010

DISTRIBUTED BY

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