SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitbee 1000, 0.100 % w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Qualitative composition	Quantitative composition
Cyanocobalamin	0.100 % w/v

Excipients

Phenol	0.500 % w/v

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

Cattle and horses, calves and foals.

4.2 Indications for use, specifying the target species

As an aid in raising Vitamin B_{12} levels in cattle and horses, calves and foals.

For use in the treatment of Vitamin B_{12} deficiency, and for poor growth rates and general unthriftiness in young animals when associated with the above deficiency.

4.3 Contraindications

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

Observe normal aseptic precautions.

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

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not contraindicated in pregnant or lactating animals.

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 and horses 1-3 ml
Calves and foals 0.5-1 ml

By intra-muscular or subcutaneous injection.
Repeat in 7 days if required.
Following treatment, the vitamin B_{12} 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 period(s)

Meat: zero days.
Milk: zero hours.

5. PHARMACOLOGICAL PROPERTIES

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 known.

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 composition of immediate packaging

50 ml type I amber glass vial, fitted with a red type I bung and

aluminium overseal.
Secondary packaging: cardboard carton.

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 36408/4012

9. DATE OF FIRST AUTHORISATION

26 February 1993

10. DATE OF REVISION OF THE TEXT

August 2021

Approved: 18/08/21