

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VITAMIN B COMPLEX PRO INJ. solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per mL:

Active ingredients:

Thiamine hydrochloride 35 mg

Riboflavin sodium phosphate 0.69 mg

Pyridoxine hydrochloride 7 mg

Cyanocobalamin 2 µg

Nicotinamide 23 mg

Ascorbic acid 70 mg

Excipients:

Benzyl alcohol 9 mg Sodium sulphite (E221) 0.5 mg Refer to Section 6.1 for the full list of excipients.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Target animal species Horses, foals, cattle, calves, sows, piglets, dogs and cats.

4.2 Indications for use with specification of the target animal species

Vitamin B and C deficiency

4.3 Contra-indications

None.

4.4 Special warnings for each animal species for which the veterinary medicinal product is intended

None

4.5 Special precautions for use Special precautions for use in animals

None.

Special precautions, to be taken by those administering the medicinal product to the animals

None.

4.6 Adverse effects (frequency and severity) None known.

4.7 Use during gestation, lactation or laying

The safety of this veterinary medicinal product has not been demonstrated during gestation and/or lactation.

4.8 Interactions with other medicinal products and other forms of interaction

No known interactions

4.9 Posology and method of administration

Subcutaneous or intra-muscular administration:

- horses: 20-30 mL
- foals: 5-10 mL
- cattle: 20-30 mL
- calves: 5-10 mL
- sows: 5-10 mL
- piglets: 1 mL
- dogs: 1-3 mL
- cats: 1-3 mL

If necessary, repeat at intervals of 12-24 hours.

4.10 Overdose (symptoms, emergency procedures, antidotes)

The toxicity of water-soluble vitamins is low; even when the recommended dose is exceeded, intoxication is unlikely to occur.

4.11 Waiting period (Offal) meat: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Vitamins ATC vet code: QA11EB

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol

Sodium sulphite

Propylene glycol

Polysorbate 80

Water for injection

6.2 Incompatibilities Do not mix with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product in the retail packaging: 12 months.

6.4 Special precautions for storage

Store at 2-8 °C (in a refrigerator).

Do not store in the freezer.

Protect against light.

6.5 Nature and composition of the primary packaging

Brown glass injection vials (type II) with rubber stopper and metal cap. Vials 12 x 100 mL, in polystyrene outer packaging.

6.6 Special precautions for the disposal of the unused veterinary medicinal product or any waste material resulting from the use of such a product.

Unused veterinary medicinal products or resulting waste should be disposed of in accordance with the national requirements.

7. NAME OF THE MARKETING AUTHORISATION HOLDER ALFASAN NETHERLANDS B.V.

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8. MARKETING AUTHORISATION NUMBER REG NL 1968

9. DATE ON WHICH AUTHORISATION WAS FIRST GRANTED/EXTENSION OF THE AUTHORISATION

Date of first authorisation: 8 September 1992

Date of last extension: 8 September 2002

10. DATE OF REVISION OF THE TEXT 5 September 2016