[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamin B_1 100 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance
Thiamine Hydrochloride 100 mg/ml

Excipients:

Qualitative composition of excipients and other constituents
Benzyl Alcohol Ph. Eur.
Sodium hydroxide
Hydrochloric acid, Concentrated
Disodium edetate
Water for Injections

A clear, colourless to greenish-yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep

3.2 Indications for use for each target species

For the treatment of cerebrocortical necrosis in cattle and sheep and as an adjunct in metabolic disorders of cattle.

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Intravenous injections should be given slowly.
Observe aseptic techniques.

3.6 Adverse events

Adverse effects are not anticipated following the administration of thiamine.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and Lactation:
It is not anticipated that the use of veterinary medicinal product will lead to any undesirable effects during pregnancy and/or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

By intramuscular or slow intravenous injection.
Dosage: 2.5 – 5 ml per 50 kg bodyweight. Repeat every 3 hours for up to a total of 5 doses.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Thiamine is very soluble in water and excess is excreted in the urine as a pyrimidine or as unchanged material. Tolerance studies have been carried out at twice the maximum recommended dose and the product was well tolerated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods
Meat : Zero days.
Milk : Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QA11DAO1

4.2 Pharmacodynamics

Vitamin B1, also known as thiamine and as aneurine, is a water soluble vitamin. Aneurine is converted in the body to aneurine pyrophosphate (cocarboxylate) which acts as a coenzyme for several decarboxylating enzyme systems, the most important of which is decarboxylase. The enzyme is necessary for the decarboxylation of pyruvic acid, an intermediate stage in carbohydrate build-up or breakdown. When carbohydrates are a major source of energy the body requirements of aneurine increase.

Tissues dependent on glucose or lactate-pyruvate for energy such as the brain and heart are particularly compromised in thiamine deficiency. Thiamine deficiency may be primary, due to deficiency in the diet, or secondary, because of destruction of the vitamin in the diet by thiaminase. The principal cause of thiamine deficiency is the presence of thiamine destroying agents which are widely distributed in nature.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 Years
Shelf-life after first opening the immediate packaging: 28 days following first broaching.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

50 ml amber Type I glass vials with a bromobutyl rubber bung and plain aluminium caps.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22033/047/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 01 October 1991

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

04/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary)