ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VitaBim B1 100 mg/ml Solution for Injection for Cattle and Sheep (IE, BE, ES, PL, FR, IT)
Vitabim Vet (DK)
Vitabim Vet 100 mg/ml Solution for Injection for Cattle and Sheep (SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Thiamine	78.68 mg
(equivalent to thiamine hydrochloride	100 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl Alcohol (E 1519)	15 mg
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

Dietary factors known to be involved in the aetiology of cerebrocortical necrosis should be addressed, these include factors affecting thiamine status (high concentrate/low roughage diet, presence of thiaminases) and high sulphur intake.

Therapy must be started early in the disease course for benefits to be achieved. If brain lesions are particularly severe or treatment is delayed, full clinical recovery may not be possible.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Intravenous injections should be given slowly.

Special precautions to be taken by the person administering the veterinary product to animals:
Care should be taken to avoid accidental self-injection. In the event of accidental self-injection, consult medical advice immediately and show the doctor this label.
Wash hands after use.
Benzyl alcohol may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to benzyl alcohol should administer the veterinary medicinal product with caution.

Special precautions for the protection of the environment:
Not applicable.

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 its local representative or the national competent authority via the national reporting system. See 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 (equivalent to 250 - 500 mg thiamine hydrochloride) per 50 kg bodyweight. Repeat every 3 hours for up to a total of 5 doses.
The stopper may be safely punctured up to 30 times.

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. Administration of the product at twice the maximum recommended dose did not induce any clinical adverse effects.

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 and offal: Zero days.
Milk: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QA11DAO1

4.2 Pharmacodynamics

Vitamin B_1, 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, or the presence of excess dietary sulphur having a detrimental effect on the animal's thiamine status.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 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.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Amber Type I glass vial closed with red bromobutyl rubber stoppers, sealed with a plain aluminium over-seal.

Package size:
Cardboard box with 1 vial of 50 ml.

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)

<To be confirmed>

8. DATE OF FIRST AUTHORISATION

DD/MM/YYYY

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

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)

ANNEX III
LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
50 ML GLASS VIAL IN A CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VitaBim B1 100 mg/ml Solution for Injection for Cattle and Sheep (IE, BE, ES, PL, FR, IT)
Vitabim Vet (DK)
Vitabim Vet 100 mg/ml Solution for Injection for Cattle and Sheep (SE)

2. STATEMENT OF ACTIVE SUBSTANCES

Thiamine	78.68 mg/ml
(equivalent to thiamine hydrochloride	100 mg/ml)

3. PACKAGE SIZE

50 ml

4. TARGET SPECIES

Cattle and sheep

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

By intramuscular or slow intravenous injection route.

7. WITHDRAWAL PERIODS

Meat and offal: Zero days.
Milk: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.
Use by …

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

14. MARKETING AUTHORISATION NUMBERS

<To be confirmed>

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

50 ML GLASS VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VitaBim B1 100 mg/ml Solution for Injection for Cattle and Sheep. (IE, BE, ES, PL, FR, IT)
Vitabim Vet (DK)
Vitabim Vet 100 mg/ml Solution for Injection for Cattle and Sheep (SE)

2. STATEMENT OF ACTIVE SUBSTANCES

Thiamine	78.68 mg/ml
(equivalent to thiamine hydrochloride	100 mg/ml)

3. TARGET SPECIES

Cattle and sheep

4. ROUTES OF ADMINISTRATION

By intramuscular or slow intravenous injection route.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal: Zero days.
Milk: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.
Use by …

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

VitaBim B1 100 mg/ml Solution for Injection for Cattle and Sheep. (IE, BE, ES, PL, FR, IT)
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Vitabim Vet 100 mg/ml Solution for Injection for Cattle and Sheep (SE)

2. Composition

Each ml contains:

Active substance:
Thiamine 78.68 mg
(equivalent to thiamine hydrochloride 100 mg)

Excipients:
Benzyl Alcohol (E1519) 15 mg

A clear, colourless to greenish-yellow solution.

3. Target species

Cattle and sheep.

4. Indications for use

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

5. Contraindications

None

6. Special warnings

Dietary factors known to be involved in the aetiology of cerebrocortical necrosis should be addressed, these include factors affecting thiamine status (high concentrate/low roughage diet, presence of thiaminases) and high sulphur intake.
Therapy must be started early in the disease course for benefits to be achieved. If brain lesions are particularly severe or treatment is delayed, full clinical recovery may not be possible.

Special precautions for use:
Intravenous injections should be given slowly.

Special precautions to be taken by the person administering the veterinary product to animals:
Care should be taken to avoid accidental self-injection. In the event of accidental self-injection, consult medical advice immediately and show the doctor this label.
Wash hands after use.
Benzyl alcohol may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to benzyl alcohol should administer the veterinary medicinal product with caution.

Special precautions for the protection of the environment:
Not applicable.

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

Overdose:
Thiamine is very soluble in water and excess is excreted in the urine as a pyrimidine or as unchanged material. Administration of the product at twice the maximum recommended dose did not induce any clinical adverse effects.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Adverse effects are not anticipated following the administration of thiamine.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: <[national system details]>.

8. Dosage for each species, routes and method of administration

By intramuscular or slow intravenous injection.
Dosage: 2.5 – 5 ml (equivalent to 250 - 500 mg thiamine hydrochloride) per 50 kg bodyweight.
Repeat every 3 hours for up to a total of 5 doses.
The stopper may be safely punctured up to 30 times.

9. Advice on correct administration

None.

10. Withdrawal periods

Meat and offal: Zero days.
Milk : Zero days

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

< To be confirmed >

Package size:
Cardboard box with 1 vial of 50 ml.

15. Date on which the package leaflet was last revised

MM/YYYY

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Bimeda Animal Health Limited
2, 3 & 4 Airton Close, Tallaght, Dublin 24, Ireland
Tel.: +353 01 4667900