IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10126/050/001**
Case No: 7001220

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Bimeda Chemicals

Broomhill Road, **Tallaght**, **Dublin 24.**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Vitamin B1 100 mg/ml Solution for Injection

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **30/09/2006**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

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 Ph. Eur.	100 mg/ml
Excipients	
Benzyl Alcohol	15 mg/ml (preservative)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

A clear, almost colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and Sheep.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Intravenous injections should be given slowly.
Observe aseptic techniques.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Adverse effects are not anticipated following administration of thiamine.

4.7 Use during pregnancy, lactation or lay

It is not anticipated that the use of Vitamin B_1 Injection will lead to any undesirable effects during pregnancy and/or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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.

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

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.

4.11 Withdrawal Period(s)

Meat: Nil. Animals may be slaughtered for human consumption following treatment.
Milk: Nil. Milk may be taken from treated animals during treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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 decarbonisation of pyruvic acid, an intermediate stage in carbohydrate build-up or breakdown. When carbohydrates are a major source of energy the body requirements for 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Sodium Hydroxide
Disodium Edetate
Water for Injections

6.2 Incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

Do not store above 25^0C. Protect from light.

6.5 Nature and composition of immediate packaging

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

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Bimeda Chemicals Ltd,
Broomhill Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10126/050/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2001/ 30th September 2006