# **ANNEX II**

Not applicable

# ANNEX III LABELLING AND PACKAGE LEAFLET

# A. LABELLING

#### PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

**Container Label** 

#### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vitamin B<sub>1</sub> 10% w/v Solution for injection.

#### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Concentration: A clear, sterile, colourless to greenish-yellow, aqueous solution for parenteral administration. Each ml contains 100 mg Thiamine Hydrochloride. Also contains 15 mg/ml Benzyl Alcohol (preservative).

#### 3. PHARMACEUTICAL FORM

Solution for injection.

#### 4. PACKAGE SIZE

50 ml

#### 5. TARGET SPECIES

Cattle and sheep

#### 6. INDICATION(S)

For the treatment of cerebrocrotical necrosis in cattle and sheep and as an adjunct in metabolic diseases of cattle.

### 7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

#### 8. WITHDRAWAL PERIOD

Withdrawl Periods; Meat: Zero days. Milk: Zero hours.

#### 9. SPECIAL WARNING(S), IF NECESSARY

Caution: Intravenous injections should be administered slowly (i.e. over 20 seconds). Observe aseptic techniques.

Pharmaceutical Warnings: Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Once broached, use by: \_\_\_/\_\_/\_\_Operator Warning: Care should be taken to avoid accidental self-injection. In the event of self-injection, consult medical advice immediately and show the doctor this label. Wash hands after use.

#### 10. EXPIRY DATE

**Expiry Date:** 

#### 11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C Protect from light

# 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

# 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For Animal Treatment Only.

To be supplied only on veterinary prescription.

POM-V

# 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

# 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited 2 / 3 / 4 Airton Close Tallaght Dublin 24 Ireland

### 16. MARKETING AUTHORISATION NUMBER

Vm 50146/4029

### 17. MANUFACTURER'S BATCH NUMBER

Batch No: Manuf. Date:

# MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

Not applicable

# MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

Not applicable

# **B. PACKAGE LEAFLET**

Not applicable.

Approved: 23 October 2018

D. Austro