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_1 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