ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>
Bottle of 100ml and 500ml, Box containing a bottle of 100ml or 500ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MULTIMIN Solution for Injection for Cattle.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains
Zinc: 60 mg, (equivalent to zinc oxide: 74.68 mg)
Manganese: 10 mg, (equivalent to manganese carbonate: 20.92 mg)
Copper: 15 mg, (equivalent to copper carbonate: 26.09 mg)
Selenium: 5 mg, (equivalent to sodium selenite: 10.95 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

Bottle of 100ml
Bottle of 500ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Indications for use

Supply of trace minerals to correct concurrent clinical or sub-clinical deficiencies of selenium, copper, manganese and zinc which can arise during critical phases of the production or breeding life cycle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Strictly for subcutaneous administration only. Do not administer intramuscularly.

Dosage:
- Cattle - Up to 1 year: 1ml per 50kg
- Cattle - From 1-2 years: 1ml per 75kg
- Cattle - Over 2 years: 1ml per 100kg

Schedule of administration

To be administered as a single administration during, or in advance of, periods of stress in the production and breeding life cycle likely to result in concurrent clinical or sub clinical deficiencies of the four trace minerals (for example, transport/shipping, calving, breeding).

Maximal volume per injection site: 7ml

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal Period

Meat and offal: 28 days
Milk: zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Special warnings

Additional copper, zinc, manganese or selenium should not be administered at the same time.
This product is HIGHLY concentrated in Selenium.
Due to a potential risk of Selenium toxicity, care should be taken when handling the product to avoid accidental self – injection.
In case of accidental self – injection, SEEK MEDICAL ADVICE IMMEDIATELY and show the package leaflet or the label to the physician**.**

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Shelf-life after first opening the immediate packaging: 28 days
Once broached, use by……...

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material in accordance with local requirements.
This section will be printed on the outer package (carton) only as it is not required on immediate package.

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

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

Keep out of the sight and reach of children.
This section will be printed on the outer package (carton) only as it is not required on immediate package.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Warburton Technology Limited
36 Fitzwilliam Square
Dublin 2
IRELAND

16. MARKETING AUTHORISATION NUMBER

Vm 42511/4000

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

MULTIMIN Solution for Injection for Cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Warburton Technology Limited
36 Fitzwilliam Square
Dublin 2
IRELAND

Manufacturer responsible for batch release:

LABORATOIRES BIOVE
Rue de Lorraine
B.P. 45
62510 ARQUES
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MULTIMIN Solution for Injection for Cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substances

Zinc:	60 mg (equivalent to zinc oxide 74.68 mg)
Manganese:	10 mg (equivalent to manganese carbonate 20.92 mg)
Copper:	15 mg (equivalent to copper carbonate 26.09 mg)
Selenium:	5 mg (equivalent to sodium selenite 10.95 mg)

Excipients

Benzyl alcohol (E1519) 10.4 mg

The product is a clear blue solution for injection

4. INDICATION(S)

Supply of trace minerals to correct concurrent clinical or subclinical deficiencies of selenium, copper, manganese and zinc which can arise during critical phases of the production or breeding life cycle.

5. CONTRAINDICATIONS

Do not administer intramuscularly.

Do not use in cases of known hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

Mild pain is commonly observed during injection and can persist for the first hour after injection.
Local reactions at the injection site are very common and consist of transient moderate to severe swelling that resolves within 48 hours and evolves into induration estimated at less than 5 cm at palpation after 14 days.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s)).
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports

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 inform your veterinary surgeon. Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Strictly for subcutaneous administration only.

Doses:
- Cattle - Up to 1 year: 1ml per 50kg
- Cattle - From 1-2 years: 1ml per 75kg
- Cattle - Over 2 years: 1ml per 100kg

Schedule of administration
To be administered as a single administration during, or in advance of, periods of stress in the production and breeding life cycle likely to result in concurrent clinical or subclinical deficiencies of the four trace minerals (for example, transport/shipping, calving, breeding).

Maximal volume per injection site: 7ml

9. ADVICE ON CORRECT ADMINISTRATION

Use standard aseptic procedures during administration of injections.
Strict adherence to correct subcutaneous injection technique should be employed.

The 500ml vial can be broached a maximum of 90 times.

10. WITHDRAWAL PERIOD

Meat and offal: 28 days
Milk: zero hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

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

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

Shelf life after first opening the container: 28 days

12. SPECIAL WARNING(S)

Special precautions for use in animals
Additional copper, zinc, manganese or selenium should not be administered at the same time.

Pregnancy and lactation
Can be used during pregnancy and lactation.

User Warnings
This product is HIGHLY concentrated in Selenium.
Due to a potential risk of Selenium toxicity, care should be taken when handling the product to avoid accidental self – injection.
The most common manifestations of accidental exposure to selenium in humans are gastrointestinal and neurological symptoms, such as nausea, vomiting, tenderness, fatigue and irritability.
When treating a large number of animals, a safe injection system should be used
Do not work alone when using the product. Ensure that animals are properly restrained, including those in the vicinity.
In case of accidental self –injection SEEK MEDICAL ADVICE IMMEDIATELY and show the package leaflet or the label to the physician.
Wash hands after use.

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

Overdose (symptoms, emergency procedures, antidotes):

No systematic adverse reactions were observed after repeated overdosing (3 consecutive daily administrations) at one to three times the recommended dose (i.e. 3x – 9x recommended dose).

Repeated overdosing (3 consecutive daily administrations) at five times the recommended dose (i.e. 15x recommended dose) is associated with elevation of liver enzymes and centrilobular hepatocellular degeneration limited to two animals out of eight.

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2021

15. OTHER INFORMATION

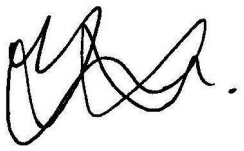
Primary packaging: Clear polyethylene terephthalate (PET) bottle closed with grey bromobutyl rubber stopper sealed with aluminium cap
Package sizes:

Cardboard box containing one vial of 100 ml

Cardboard box containing one vial of 500 ml

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the marketing authorisation holder



Approved: 08 April 2021