

**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 breached, 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

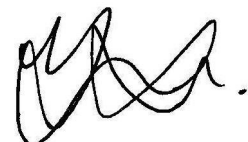
Package sizes:

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