Mebendazole 500 mg Chewable Tablets (Janssen-Cilag International NV), NT006

# LABELLING

1

#### PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING Bottle label (HDPE bottle)

#### 1. NAME OF THE MEDICINAL PRODUCT

#### VERMOX CHEWABLE<sup>1</sup>

### 2. STATEMENT OF ACTIVE SUBSTANCE

500 mg mebendazole chewable tablets

## **3.** LIST OF EXCIPIENTS

## 4. PHARMACEUTICAL FORM AND CONTENTS

200 chewable tablets

### 5. METHOD AND ROUTE OF ADMINISTRATION

Oral use - Read the package leaflet before use.

## 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the sight and reach of children.

## 7. OTHER SPECIAL WARNING(S), IF NECESSARY

## 8. EXPIRY DATE

Expiry: {MM/YYYY}

## 9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.Keep container tightly closed.

Discard tablets 3 months after opening the bottle. Date opened \_\_\_\_/\_\_\_.

<sup>&</sup>lt;sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

### 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

### 11. NAME AND ADDRESS OF THE SUPPLIER

Manufactured by: Lusomedicamenta Lisbon, Portugal

Manufactured for: Janssen-Cilag International NV Turnhoutseweg 30 B-2340 Beerse Belgium

## 12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

NT006

### **13. MANUFACTURER'S BATCH NUMBER**

<Batch><Lot><BN> {number}

## 14. <ADVICE ON> GENERAL CLASSIFICATION FOR SUPPLY

Not for resale.

## **15. INSTRUCTIONS ON USE**