

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

### **Plastic (HDPE) bottle**

#### **1. Name of the medicinal product**

[HA526 trade name]\* Zidovudine 50 mg/5 mL oral solution  
Zidovudine

#### **2. Statement of active substance**

Each 5 mL of oral solution contains 50 mg zidovudine.

#### **3. List of excipients**

Contains sucrose.

See patient information leaflet for further information.

#### **4. Pharmaceutical form and contents**

Oral solution

240 mL

100 mL

#### **5. Method and route of administration**

Oral use.

Read the patient information leaflet before use.

#### **6. Special warning that the medicinal product must be stored out of the reach and sight of children**

Keep this medicine out of the sight and reach of children.

#### **7. Other special warning(s), if necessary**

#### **8. Expiry date**

EXP {MM/YYYY}

#### **9. Special storage conditions**

Store tightly closed in the original bottle. Do not store above 30°C.

Discard the solution 28 days after first opening.

#### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

---

\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

**11. Name and address of the supplier**

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade  
Marol Church road  
Andheri (East)  
Mumbai – 400 059,  
India.  
Tel: +91-22-66762800  
Fax: +91 -22-28216599  
Email: sjadhav@macleodspharma.com

**12. WHO Reference Number (Prequalification Programme)**

HA526

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

**14. (Advice on) General classification for supply**

Medicinal product subject to medical prescription.

**15. Instructions on use**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

### **Carton label**

#### **1. Name of the medicinal product**

[HA526 trade name]<sup>†</sup> Zidovudine 50 mg/5 mL oral solution  
Zidovudine

#### **2. Statement of active substance**

Each 5 mL of oral solution contains 50 mg zidovudine.

#### **3. List of excipients**

Contains sucrose.

See patient information leaflet for further information.

#### **4. Pharmaceutical form and contents**

Oral solution

240 mL

100 mL

#### **5. Method and route of administration**

Oral use.

Read the patient information leaflet before use.

#### **6. Special warning that the medicinal product must be stored out of the reach and sight of children**

Keep this medicine out of the sight and reach of children.

#### **7. Other special warning(s), if necessary**

#### **8. Expiry date**

EXP {MM/YYYY}

#### **9. Special storage conditions**

Store tightly closed in the original bottle Do not store above 30°C.

Discard the solution 28 days after first opening.

#### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

---

<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

**11. Name and address of the supplier**

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade  
Marol Church road  
Andheri (East)  
Mumbai 400 059,  
India.  
Tel: +91-22-66762800  
Fax: +91 -22-28216599  
Email: sjadhav@macleodspharma.com

**12. WHO Reference Number (Prequalification Programme)**

HA526

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

**14. (Advice on) General classification for supply**

Medicinal product subject to medical prescription.

**15. Instructions on use**