# LABELLING

# PARTICULARS TO APPEAR ON THE OUTER PACKAGING HDPE Bottle Label

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

[TB307 trade name]<sup>1</sup> Pyrazinamide 150 mg dispersible tablets Pyrazinamide

#### 2. Statement of active substance

Each tablet contains 150 mg of pyrazinamide

#### 3. List of excipients

Each tablet contains 2mg aspartame. See patient information leaflet for further information

### 4. Pharmaceutical form and contents

100 tablets

#### 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 below 30°C, in dry place. Protect from light.

# **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

Macleods Pharmaceuticals Limited Block N2, Village Theda, Post Office Lodhimajra Tehsil Baddi, District Solan

<sup>&</sup>lt;sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Pyrazinamide 150mg dispersible tablets (Macleods Pharmaceuticals Ltd), TB307

Himachal Pradesh – 174101 India Phone: +91 1795 661400 Fax: +91 1795 661452

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

TB307

# 13. Manufacturer's batch number

<Batch> {number}

# 14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

### **15. Instructions on use**

# MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING SACHETS

## 1. Name of the medicinal product

[TB307 trade name]<sup>2</sup> Pyrazinamide 150 mg dispersible tablets Pyrazinamide

## 2. Name of the supplier

Macleods Pharmaceuticals Ltd

## 3. Expiry date

EXP {MM/YYYY}

## 4. Manufacturer's batch number

<Batch> {number}

<sup>&</sup>lt;sup>2</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.