

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND ON THE IMMEDIATE PACKAGING**

**Alu/PET/Alu/LLDPE sachet, LDPE bag, HDPE bottle**

**1. NAME OF THE MEDICINAL PRODUCT**

Para-aminosalicylate sodium delayed-release granules 60% w/w \*

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each bottle contains: p-aminosalicylate sodium delayed-release granules (60% w/w) 100 g, (equivalent to 43.5 grams p-aminosalicylic acid)

Each sachet contains: p-aminosalicylate sodium delayed-release granules (60% w/w) 9.2 g, (equivalent to 4 grams p-aminosalicylic acid)

**3. LIST OF EXCIPIENTS**

Contains hydrogenated castor oil and sodium metabisulphite. See patient information leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Enteric coated granules

**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 out of the sight and reach of children.

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

\* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

**8. EXPIRY DATE**

EXP {MM/YYYY}

**9. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C. Store in a dry place, protected 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 Ltd  
304, Atlanta Arcade  
Marol Church Road  
Andheri (East)  
Mumbai 400 059  
India  
Phone: +91-22-56762800  
Fax: +91-22-2821 6599  
E-mail: [exports@macleodspharma.com](mailto:exports@macleodspharma.com)

**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

TB156

**13. MANUFACTURER'S BATCH NUMBER**

Batch No.:

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**