

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**CARTON (Blister)**

**1. NAME OF THE MEDICINAL PRODUCT**

[MA125 trade name]<sup>1</sup>

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each tablet contains 67.5 mg Amodiaquine (as hydrochloride) and 25 mg Artesunate

**3. LIST OF EXCIPIENTS**

See the patient information leaflet for further information

**4. PHARMACEUTICAL FORM AND CONTENTS**

3 Tablets (1 x 3 Tablets)

75 Tablets (25 x 3 Tablets)

100 Tablets (10 x 10 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}

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

**9. SPECIAL STORAGE CONDITIONS**

Store below 30° C. Store in a 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  
Phase II and Phase III, Unit II  
Plot No 25-27, Survey No 366  
Premier Industrial Estate  
Kachigam, Daman,  
396 210, India

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

MA125

**13. MANUFACTURER'S BATCH NUMBER**

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

**MINIMUM PARTICULARS TO APPEAR ON BLISTER**

**1. NAME OF THE MEDICINAL PRODUCT**

[MA125 trade name]

**2. NAME OF THE SUPPLIER**

Macleods Pharmaceuticals Limited

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

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