

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON (Blister)

1. NAME OF THE MEDICINAL PRODUCT

[MA127 trade name]¹

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains 270 mg Amodiaquine (as hydrochloride) and 100 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)

6 Tablets (1 x 6 Tablets)

75 Tablets (25 x 3 Tablets)

100 Tablets (10 x 10 Tablets)

150 Tablets (25 x 6 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 out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

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

EXP {MM/YYYY}

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)

MA127

13. MANUFACTURER'S BATCH NUMBER

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

MINIMUM PARTICULARS TO APPEAR ON BLISTER

1. NAME OF THE MEDICINAL PRODUCT

[MA127 trade name]

2. NAME OF THE SUPPLIER

Macleods Pharmaceuticals Limited

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

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