

LABELING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING outer carton

1. NAME OF THE MEDICINAL PRODUCT

Artesunate/Mefloquine 25/50mg FDC (Fixed Dose Combination) Cipla Tablets *

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains 25 mg artesunate and 50 mg mefloquine (as hydrochloride).

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

1 x 3 tablets
2 x 3 tablets

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use
Read the package 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

* Trade names are not prequalified by WHO. This is under local drug regulatory authority's 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 30°C.

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

Cipla Ltd
Mumbai Central
Mumbai 400008
Maharashtra, India
Phone: (9122)23082891
Fax: (9122) 23070013
Email: exports@cipla.com

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

MA078

13. MANUFACTURER'S BATCH NUMBER

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

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

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3. EXPIRY DATE

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