

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA078 trade name]* Artesunate/ Mefloquine (as hydrochloride) 25 mg/50 mg Tablets
Artesunate/ Mefloquine (as hydrochloride)

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

Tablets

1 x 3 tablets

2 x 3 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

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 product, is, if appropriate

11. Name and address of the supplier

Drugs for Neglected Diseases Initiative (DNDi)
15 Chemin Louis Dunant Geneva, 1202
Switzerland

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

[#] Formerly known as Cipla Limited

12. WHO Reference Number (Prequalification Programme)

MA078

13. Manufacturer's batch number

<Batch> <Lot> {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 STRIP
ALUMINIUM-ALUMINIUM BLISTER STRIP

1. Name of the medicinal product

[MA078 trade name] Artesunate/ Mefloquine (as hydrochloride) 25 mg/50 mg Tablets
Artesunate/ Mefloquine (as hydrochloride)

2. Name of the supplier

Cipla Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other