

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[MA125 trade name]* Amodiaquine (hydrochloride)/artesunate 67.5 mg/25 mg tablets
Amodiaquine (as hydrochloride)/artesunate

2. Statement of active substance

Each tablet contains 67.5 mg amodiaquine (hydrochloride) and 25 mg artesunate

3. List of excipients

4. Pharmaceutical form and contents

Tablet

1 x 3 tablets

25 x 3 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}

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
304 Atlanta Arcade

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

Amodiaquine (hydrochloride)/artesunate
67.5 mg/25 mg tablets
(Macleods Pharmaceuticals Limited), MA125

WHOPAR Part 5

March 2025

Marol Church Road
Andheri (East)
Mumbai – 400 059
India

12. WHO Reference Number (Prequalification Programme)

MA125

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

Alu/Alu blisters

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Amodiaquine (as hydrochloride)/artesunate

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other