Amodiaquine (as hydrochloride)/ Artesunate
67.5mg/25 mg tablets (Ipca Laboratories Ltd),
MA080

WHOPAR part 5

April 2025

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
CARTON LABEL

1. Name of the medicinal product

[MA080 trade name][1] Amodiaquine (as hydrochloride) /Artesunate 67.5 mg/25 mg Tablets

Amodiaquine (as hydrochloride)/Artesunate

2. Statement of active substance

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

3. List of excipients

Each tablet contains 10.25 mg lactose monohydrate.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Bi-layered tablet

10 x 1 x 3 tablets
25 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 sight and reach 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 products, if appropriate

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

Amodiaquine (as hydrochloride)/ Artesunate
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WHOPAR part 5

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11. Name and address of the supplier

Ipca Laboratories Ltd
48 Kandivli Ind. Estate
Kandivli (West)
400 067 Mumbai
India
Tel: 91 - 22-6210-5100/91-22-6210-5000

12. WHO Reference Number (Prequalification Programme)

MA080

13. Manufacturer's batch number

<Batch> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

Amodiaquine (as hydrochloride)/ Artesunate
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MA080

WHOPAR part 5

April 2025

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

1. Name of the medicinal product

[MA080 trade name] Amodiaquine (as hydrochloride)/Artesunate 67.5mg/25mg Tablets
Amodiaquine (as hydrochloride)/Artesunate

2. Name of the supplier

Ipca Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}