LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
CARTON LABEL

1. Name of the medicinal product

[MA082 trade name]* Artesunate & Amodiaquine Tablets 100 mg/270 mg

Artesunate/Amodiaquine (as hydrochloride)

2. Statement of active substance

Each bilayer tablet contains artesunate Ph.Int 100 mg and amodiaquine hydrochloride USP equivalent to amodiaquine base 270 mg

3. List of excipients

Contains lactose. See patient information leaflet for further information.

4. Pharmaceutical form and contents

10 x 1 x 3 tablets
10 x 1 x 6 tablets
25 x 3 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 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

11. Name and address of the supplier

Ipca Laboratories Ltd

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

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)

MA082

13. Manufacturer's batch number

<Batch> {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

1. Name of the medicinal product

[MA082 trade name]† Artesunate & Amodiaquine Tablets (100 mg/270 mg)

Artesunate/Amodiaquine (as hydrochloride)

2. Name of the supplier

Ipca Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}

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