

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton Label

1. Name of the medicinal product

[MA081 trade name]* Artesunate & Amodiaquine (as hydrochloride) 50 mg/135 mg Tablets

Artesunate/Amodiaquine (as hydrochloride)

2. Statement of active substance

Each bilayer tablet contains artesunate Ph.Int. 50 mg and amodiaquine (as hydrochloride) USP equivalent to amodiaquine base 135 mg

3. List of excipients

Contains lactose.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

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

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

11. Name and address of the supplier

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

12. WHO Reference Number (Prequalification Programme)

MA081

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

Blister

1. Name of the medicinal product

[MA081 trade name] Artesunate & Amodiaquine (as hydrochloride) 50 mg/135 mg Tablets
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}