

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA190 trade name]* Amodiaquine (as hydrochloride) 153 mg dispersible tablets +
Pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets
Amodiaquine (as hydrochloride) + Pyrimethamine/sulfadoxine

2. Statement of active substance

Each amodiaquine (as hydrochloride) dispersible tablet contains 153 mg amodiaquine (as hydrochloride) and each pyrimethamine/ sulfadoxine dispersible tablet contains 25 mg pyrimethamine and 500 mg sulfadoxine.

3. List of excipients

See patient information leaflet

4. Pharmaceutical form and contents

Dispersible tablets

25 x 4 (3+1)

50 x 4 (3+1)

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

Do not store above 30°C. Protect from light. Store the tablets in blisters in the provided box or carton.

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

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 Limited
48, Kandivli Industrial Estate
Kandivli (W), Mumbai 400 067
India
Tel : +91-22-6210 5000/+91-22-6210 5100
Fax : /+91-22-6210 5005

12. WHO Reference Number (Prequalification Programme)

MA190

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

PVC/Alu blister

1. Name of the medicinal product

[MA190 trade name] Amodiaquine (as hydrochloride) 153 mg dispersible tablets +
Pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets

Amodiaquine (as hydrochloride) + Pyrimethamine/sulfadoxine

2. Name of the supplier

Ipca Laboratories Limited

3. Expiry date

EXP {MM/YY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other