

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA197 trade name]*

Amodiaquine (as hydrochloride) 76.5 mg dispersible tablets + Pyrimethamine/Sulfadoxine 12.5 mg/250 mg dispersible tablet

Amodiaquine (as hydrochloride) + Pyrimethamine/Sulfadoxine

2. Statement of active substance

Each amodiaquine (as hydrochloride) dispersible tablet contains 76.5 mg amodiaquine (as hydrochloride) and

Each pyrimethamine/sulfadoxine dispersible tablet contains 12.5 mg pyrimethamine and 250 mg sulfadoxine.

3. List of excipients

See patient information leaflet.

4. Pharmaceutical form and contents

Dispersible tablets

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. Store tablets in blisters in the provided carton. Protect from light and moisture. Avoid excursion 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

Ajanta Pharma Ltd.

Ajanta House, Charkop

Kandivli (West), Mumbai – 400067

India

12. WHO Reference Number (Prequalification Programme)

MA197

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

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

[MA197 trade name]

Amodiaquine (as hydrochloride) 76.5 mg dispersible tablets + Pyrimethamine/Sulfadoxine
12.5 mg/250 mg dispersible tablets

2. Name of the supplier

Ajanta Pharma Ltd.

3. Expiry date

EXP {MM/YY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other