

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

### **Carton**

**1. Name of the medicinal product**

[MA198 trade name]\*

Amodiaquine (as hydrochloride) 153 mg dispersible tablet + 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).

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

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)**

MA198

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\* 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**

[MA198 trade name]

Amodiaquine (as hydrochloride) 153 mg dispersible tablet + Pyrimethamine/Sulfadoxine 25 mg/500 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**