

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

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

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.

List of excipients

See patient information leaflet.

Pharmaceutical form and contents

Dispersible tablets
50 x 4 (3+1)

Method and route of administration

Oral use.
Read the patient information leaflet before use.

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.

1. Other special warning(s), if necessary

Expiry date

EXP {MM/YYYY}

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.

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

2. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

Name and address of the supplier

Ajanta Pharma Ltd.
Ajanta Tower
54-A, M VasANJI Road
Chakala
Andheri (E)
Mumbai – 400 093
India

WHO Reference Number (Prequalification Programme)

MA198

Manufacturer's batch number

<Batch> <Lot> {number}

(Advice on) General classification for supply

Medicinal product subject to medical prescription.

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
Amodiaquine (as hydrochloride) + pyrimethamine/sulfadoxine

2. Name of the supplier

Ajanta Pharma Limited.

3. Expiry date

EXP {MM/YY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other