

## **LABELLING**

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

### **Outer carton**

#### **1. Name of the medicinal product**

[MA170 trade name]\*

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

#### **2. Statement of active substance**

*Amodiaquine (as hydrochloride) 76.5 mg dispersible tablets*

Each tablet contains 76.5 mg amodiaquine (as hydrochloride)

*Pyrimethamine/Sulfadoxine 12.5 mg/ 250 mg dispersible tablets*

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

#### **3. List of excipients**

*Amodiaquine (as hydrochloride) 76.5 mg dispersible tablets*

Each tablet contains aspartame, lactose monohydrate and sodium

*Pyrimethamine/Sulfadoxine 12.5 mg/ 250 mg dispersible tablets*

Each tablet contains aspartame and sodium

See the patient information leaflet for further information.

#### **4. Pharmaceutical form and contents**

Dispersible tablets

50 blister cards

3 x Amodiaquine (as hydrochloride) 76.5 mg tablets and 1 x Pyrimethamine/Sulfadoxine 12.5 mg/250 mg tablets per blister

#### **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 reach and sight of children.

#### **7. Other special warning(s), if necessary**

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

**8. Expiry date**

EXP {MM/YYYY}

**9. Special storage conditions**

Do not store above 30°C. Store tablets in blisters in the provided carton in order to protect from light.

**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**

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade,  
Marol Church Road,  
Andheri (East), Mumbai  
400 059, India

**12. WHO Reference Number (Prequalification Programme)**

MA170

**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**

### **Clear PVC/PVDC-Alu blisters**

#### **1. Name of the medicinal product**

[MA170 trade name]<sup>†</sup>

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

#### **2. Name of the supplier**

Macleods Pharmaceuticals Limited

#### **3. Expiry date**

EXP {MM/YYYY}

#### **4. Manufacturer's batch number**

<Batch> <Lot>{number}

#### **5. Other**

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