

## **LABELLING**

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

Carton

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

[MA189 trade name]\* Amodiaquine (as hydrochloride) 76.5 mg dispersible tablets +  
Pyrimethamine/sulfadoxine 12.5 mg/250 mg dispersible tablets  
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

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.

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\* 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)**

MA189

**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**

[MA189 trade name] Amodiaquine (as hydrochloride) 76.5 mg dispersible tablets +  
Pyrimethamine/sulfadoxine 12.5 mg/250 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**