

## **LABELLING**

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

Blister carton

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

[MA126 trade name]\* Amodiaquine (hydrochloride)/artesunate 135 mg/50 mg tablets  
Amodiaquine (as hydrochloride)/artesunate

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

Each tablet contains 135 mg amodiaquine (hydrochloride) and 50 mg artesunate

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

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

Tablet

1 x 3 tablets

25 x 3 tablets

10 x 10 tablets

### **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**

Store below 30°C. Store in a dry place. 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

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

Amodiaquine (hydrochloride)/artesunate  
135 mg/50 mg tablets  
(Macleods Pharmaceuticals Limited), MA126

WHOPAR Part 5

April 2025

Marol Church Road  
Andheri (East)  
Mumbai – 400 059  
India

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

MA126

**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**

Alu/Alu blisters

**1. Name of the medicinal product**

[MA126 trade name] Amodiaquine (hydrochloride)/artesunate 135 mg/50 mg tablets  
Amodiaquine (as hydrochloride)/artesunate

**2. Name of the supplier**

Macleods Pharmaceuticals Limited

**3. Expiry date**

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**