

## **LABELLING**

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

### **Carton of blister pack**

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

[MA104 trade name]

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

Each tablet contains 100 milligrams of artesunate and amodiaquine hydrochloride equivalent to 270 milligrams of amodiaquine.

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

Contains lactose. See patient information leaflet for further information.

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

3 tablets (1x3)

6 tablets (1x6)

#### **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.

#### **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**

Cipla Limited  
Cipla House,  
Peninsula Business Park,  
Ganpatrao Kadam Marg,  
Lower Parel, Mumbai- 400013,

India  
Phone: 91-22-24826000  
Fax: 91-22-24826120

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

MA104

**13. Manufacturer's batch number**

<Batch> <Lot> <BN> {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**

**1. Name of the medicinal product**

[MA104 trade name]

**2. Name of the supplier**

Cipla Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> <BN>{number}

**5. Other**