

## **LABELLING**

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

PVC/Aclar/PVC-Alu blisters

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

[MA115 trade name]\*

Artemether/lumefantrine 20 mg/120 mg dispersible tablets

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

Each dispersible tablet contains 20 mg artemether and 120 mg lumefantrine.

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

See the patient information leaflet for further information.

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

Dispersible tablets:

Carton containing blister of 6 tablets

Carton containing blister of 12 tablets

Carton containing blister of 18 tablets

Carton containing 30 blisters of 6 tablets each.

Carton containing 30 blisters of 12 tablets each

Carton containing 30 blisters of 18 tablets each

### **5. Method and route of administration**

Oral use.

Do not chew.

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 tablets in blisters in the provided 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**

Cipla Ltd  
Cipla House  
Peninsula Business Park  
Ganpatrao Kadam Marg  
Lower Parel  
Mumbai, Maharashtra, 400 013  
India

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

MA115

**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/Aclar/PVC-Alu blisters

**1. Name of the medicinal product**

[MA115 trade name]

Artemether/lumefantrine 20 mg/120 mg dispersible tablets

**2. Name of the supplier**

Cipla Ltd

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**