

## **LABELLING**

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

Blister carton

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

[MA062 trade name]\* Artemether/Lumefantrine 20 mg/120 mg Tablets  
Artemether/Lumefantrine

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

Each tablet contains 20 mg artemether and 120 mg lumefantrine

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

The tablets contain lactose anhydrous.  
See patient information leaflet for further information.

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

1 x 6 tablets  
2 x 6 tablets  
3 x 6 tablets  
4 x 6 tablets

30 x 6 tablets  
30 x 12 tablets  
30 x 18 tablets  
30 x 24 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}

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

**9. Special storage conditions**

Do not store above 30°C. Store in the original package 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**

Ipca Laboratories Ltd  
International House  
48 Kandivli Industrial Estate  
Kandivli (West)  
400 067, Mumbai  
India

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

MA062

**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-PVDC/Aluminium blisters

**1. Name of the medicinal product**

[MA062 trade name] Artemether/Lumefantrine 20 mg/120 mg Tablets

Artemether/Lumefantrine

**2. Name of the supplier**

Ipca Laboratories Ltd

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**