

## **LABELLING**

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

### **Carton**

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

[MA160 trade name]\* Artemether / Lumefantrine 80 mg /480 mg Tablets

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

Each tablet contains 80 mg artemether and 480 mg lumefantrine

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

Each tablet contains lactose.

See patient information leaflet for further information.

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

Tablets

1 x 6 tablets

30 x 6 tablets

30 x 1 x 6 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**

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**

Ipca Laboratories Limited

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

48, Kandivli Industrial Estate  
Kandivli (West)  
Mumbai 400 067  
India

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

MA160

**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**

Alu-Alu blister

**1. Name of the medicinal product**

[MA160 trade name] Artemether / Lumefantrine 80 mg / 480 mg Tablets

**2. Name of the supplier**

Ipca Laboratories Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**