

## **LABELLING**

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

Carton / Outer printed box

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

[MA167 trade name]\*

Artemether/lumefantrine 20 mg/120 mg tablets

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

Artemether/lumefantrine 20 mg/120 mg tablets

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

Each tablet contains anhydrous lactose

See the patient information leaflet for further information.

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

Tablets.

Carton containing 1 blister of 6 tablets

Carton containing 2 blisters of 6 tablets

Carton containing 3 blisters of 6 tablets

Carton containing 4 blisters of 6 tablets

Outer printed box containing 30 monocartons with 1 blister of 6 tablets

Outer printed box containing 30 monocartons with 1 blister of 12 tablets

Outer printed box containing 30 monocartons with 1 blister of 18 tablets

Outer printed box containing 30 monocartons with 1 blister of 24 tablets

Outer printed box containing 30 blisters of 6 tablets

Outer printed box containing 30 blisters of 12 tablets

Outer printed box containing 30 blisters of 18 tablets

Outer printed box containing 30 blisters of 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}

**9. Special storage conditions**

Do not store above 30°C. Protect from light. Store in the original packaging.

**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**

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

MA167

**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**  
**Clear PVDC/PVC-Alu blister cards or clear PVC/PVDC-Alu blister cards**

**1. Name of the medicinal product**

[MA167 trade name]

Artemether/lumefantrine 20 mg/120 mg tablets

**2. Name of the supplier**

Laboratórios Basi - Indústria Farmacêutica, S.A.

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**