

## **LABELLING**

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

### **Carton label**

**1. Name of the medicinal product**

[MA210 trade name]\* Artemether/lumefantrine 80 mg/480 mg tablets  
Artemether/lumefantrine

**2. Statement of active substance**

Each uncoated tablet contains 80 mg artemether and 480 mg lumefantrine

**3. List of excipients**

**4. Pharmaceutical form and contents**

Tablet

1 × 6 tablets

30 × 6 tablets

10 × 15 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 tablets in blisters in the provided carton.

**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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

**11. Name and address of the supplier**

Velvet Med-Healthcare Solution S.A  
Estrada Nacional 118, Km 38.8  
Edifício Mulemba  
2130-073 Benavente  
Portugal

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

MA210

**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**

Alu-PVC/PE/PVDC blisters

**1. Name of the medicinal product**

[MA210 trade name] Artemether/lumefantrine 80 mg/480 mg tablets  
Artemether/lumefantrine

**2. Name of the supplier**

Velvet Med-Healthcare Solution S.A

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

**5. Other**