LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Blister carton

1. **Name of the medicinal product**

   [MA064 trade name]* Artemether / Lumefantrine 20mg/120mg tablets

2. **Statement of active substance**

   Each tablet contains artemether 20 mg and lumefantrine 120 mg

3. **List of excipients**

   See patient information leaflet for further information.

4. **Pharmaceutical form and contents**

   Tablets

   Aluminium-aluminium blister pack:
   1 x 6 tablets
   2 x 6 tablets
   3 x 6 tablets
   4 x 6 tablets

   Aluminium- Aclar blister pack:
   1 x 6 tablets
   1 x 12 tablets
   1 x 18 tablets
   1 x 24 tablets
   30 x 6 tablets
   30 x12 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. Protect from light. Store in the original package.

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)**

MA064

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

1. **Name of the medicinal product**
   [MA064 trade name] Artemether / Lumefantrine 20mg/120mg tablets

2. **Name of the supplier**
   Cipla Ltd

3. **Expiry date**
   EXP {MM/YYYY}

4. **Manufacturer's batch number**
   <Batch> <Lot>{number}

5. **Other**