LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA211 trade name]* Artemether/Lumefantrine 20mg/120mg uncoated tablets

Artemether and lumefantrine

2. Statement of active substance

Each uncoated tablet contains 20 mg artemether and 120 mg lumefantrine

3. List of excipients

See the patient leaflet for further information

4. Pharmaceutical form and contents

Uncoated Tablets

1×6 and 30×6

1×12 and 30×12

1×18 and 30×18

1×24 and 30×24

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.

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

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

Quality Chemical Industries Limited
Plot 1-7, 1st Ring Road,
Luzira Industrial Park,
P.O. Box 34871,
Kampala-Uganda.
Email: contactus@qcil.com

12. WHO Reference Number (Prequalification Programme)

MA211

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

Blister cards (Aluminium /PVC-Aclar)

1. Name of the medicinal product

[MA211 trade name] Artemether/Lumefantrine 20mg/120mg uncoated tablets

Artemether and lumefantrine

2. Name of the supplier

Quality Chemical Industries Limited

3. Expiry date

EXP: {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other