

## **LABELLING**

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

Carton

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

[MA169 trade name]\* Amodiaquine (as hydrochloride) 150 mg dispersible tablets +  
Pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets

Amodiaquine (as hydrochloride) + Pyrimethamine/sulfadoxine

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

Each amodiaquine (as hydrochloride) dispersible tablet contains 150 mg amodiaquine and each pyrimethamine/ sulfadoxine dispersible tablet contains 25 mg pyrimethamine and 500mg sulfadoxine.

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

Contains lactose

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

Dispersible tablets

25 x 4

30 x 4

50 x 4

### **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. Avoid excursions above 30°C. Protect from light and moisture. Store the tablets in blisters in the provided box or carton.

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\* 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**

Universal Corporation Limited  
Club Road, Plot No. 13777  
P.O.Box 1748-00902  
Kikuyu,  
Kenya.  
Tel: +254 20 2693835 / 20 2693836  
Email: info@ucl.co.ke

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

MA169

**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**

PVC/PVDC-Alu blister card

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[MA169 trade name] Amodiaquine (as hydrochloride) 150 mg dispersible tablets+  
Pyrimethamine/Sulfadoxine 25 mg/500 mg dispersible tablets

Amodiaquine (as hydrochloride) + Pyrimethamine/Sulfadoxine

**2. Name of the supplier**

Universal Corporation Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**