

## **LABELLING**

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

Blister carton

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

[MA146 trade name] Amodiaquine (as hydrochloride) 75mg dispersible tablets +  
Pyrimethamine/Sulfadoxine 12.5mg/250mg dispersible tablet

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

Contains three Amodiaquine (as hydrochloride) 75mg dispersible tablets and one  
Pyrimethamine/Sulfadoxine 12.5mg/250mg dispersible tablet

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

*Amodiaquine (as hydrochloride) 75mg dispersible tablets*

Contains mannitol.

*Pyrimethamine/Sulfadoxine 12.5mg/250mg dispersible tablet*

Contains isomalt.

See the patient information leaflet for further information.

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

Dispersible tablets

1 x 4 x 25 tablets

1 x 4 x 50 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 out of the 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. Store tablets in blisters in the provided carton in order to protect from light.

**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**

S Kant Healthcare Ltd.  
3-A, Shiv Sagar Estate,  
North Wing,  
Dr. Annie Besant Road,  
Worli, Mumbai 400018  
India

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

MA146

**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-Al blisters

**1. Name of the medicinal product**

[MA146 trade name]

Amodiaquine (as hydrochloride) + Pyrimethamine/Sulfadoxine

**2. Name of the supplier**

S Kant Healthcare Ltd

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**