

## **LABELLING**

## PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

### 1. Name of the medicinal product

[MA147 trade name]\* Amodiaquine (as hydrochloride) 150 mg dispersible tablets +  
Pyrimethamine/Sulfadoxine 25 mg/500 mg dispersible tablet

### 2. Statement of active substance

Contains three Amodiaquine (as hydrochloride) 150 mg dispersible tablets and one  
Pyrimethamine/Sulfadoxine 25 mg/500 mg dispersible tablet

### 3. List of excipients

*Pyrimethamine/Sulfadoxine 25 mg/500 mg 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 this medicine out of 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.

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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**

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)**

MA147

**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**

[MA147 trade name] Amodiaquine (as hydrochloride) 150 mg dispersible tablets +  
Pyrimethamine/Sulfadoxine 25 mg/500 mg dispersible tablet

**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**