

## **LABELLING**

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

Outer carton

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

[MA196 trade name]\* Primaquine (as phosphate) 15 mg tablets  
Primaquine phosphate

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

Each film-coated tablet contains 15 mg primaquine phosphate

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

Each film-coated tablet contains about 43.15 mg of lactose.  
See patient information leaflet for further information

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

Film-coated tablets  
1x7 tablets  
10x7 tablets

### **5. Method and route of administration**

Oral use.  
Do not chew.  
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.

### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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

**11. Name and address of the supplier**

Ipca Laboratories Limited  
48, Kandivli Industrial Estate  
Kandivli (W)  
Mumbai 400 067  
India

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

MA196

**13. Manufacturer's batch number**

<Batch> {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**

**1. Name of the medicinal product**

[MA196 trade name] Primaquine (as phosphate) 15 mg tablets

Primaquine phosphate

**2. Name of the supplier**

Ipca Laboratories Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch>{number}

**5. Other**