

## **LABELLING**

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

Outer carton

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

[MA176 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 60 mg of lactose monohydrate.  
See patient information leaflet for further information

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

Film-coated tablets  
10x10 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 25°C. Avoid excursions above 30°C.

### **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**

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade  
Marol Church road  
Andheri (East)  
Mumbai – 400 059, India.

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

MA176

**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

### 1. Name of the medicinal product

[MA176 trade name]<sup>†</sup>Primaquine (as phosphate) 15 mg tablets

Primaquine phosphate

### 2. Name of the supplier

Macleods Pharmaceutical Ltd

### 3. Expiry date

EXP {MM/YYYY}

### 4. Manufacturer's batch number

<Batch><Lot>{number}

### 5. Other

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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

HDPE bottle label

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

[MA176 trade name]<sup>‡</sup> 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 60 mg of lactose monohydrate.

See patient information leaflet for further information

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

Film coated tablets

100 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 25°C. Avoid excursions above 30°C.

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

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<sup>‡</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade  
Marol Church road  
Andheri (East)  
Mumbai – 400 059, India.

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

MA176

**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**