LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[MA208 trade name][*] Primaquine (phosphate) 7.5mg dispersible tablets

Primaquine phosphate

2. Statement of active substance

Each dispersible tablet contains 7.5mg primaquine (phosphate)

3. List of excipients

Each dispersible tablet contains 18.65mg of lactose.

See patient information leaflet for further information

4. Pharmaceutical form and contents

Dispersible tablet

2 x 7 tablets

24 x 7 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.

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

[*] 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
T: +91-22-6210 5000
F: 91-22-6210 5105/+91-22-6210 5005

12. WHO Reference Number (Prequalification Programme)

MA208

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

[MA208 trade name] Primaquine (phosphate) 7.5mg dispersible 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