Amodiaquine + pyrimethamine/sulfadoxine
75mg + 12.5mg/250mg dispersible tablets
(S Kant Healthcare Ltd), MA146

WHOPAR Part 5

October 2024

LABELLING

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PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[MA146 trade name] Amodiaquine (as hydrochloride) 75 mg dispersible tablets +

Pyrimethamine/Sulfadoxine 12.5 mg/250 mg dispersible tablet

2. Statement of active substance

Contains three Amodiaquine (as hydrochloride) 75 mg dispersible tablets and one

Pyrimethamine/Sulfadoxine 12.5mg/250mg dispersible tablet

3. List of excipients

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.

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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

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

PVC/PVDC-Al blisters

1. **Name of the medicinal product**

   [MA146 trade name]

   Amodiaquine (as hydrochloride) 75 mg dispersible tablets + Pyrimethamine/Sulfadoxine

   12.5 mg/250 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**