

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[MA193 trade name]* Pyrimethamine/sulfadoxine 25 mg/500 mg tablets
Pyrimethamine/sulfadoxine

2. Statement of active substance

Each pyrimethamine/ sulfadoxine tablet contains 25 mg pyrimethamine and 500 mg sulfadoxine.

3. List of excipients

See patient information leaflet

4. Pharmaceutical form and contents

Tablets
30 x 3

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 the sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Avoid excursions above 30°C. Protect from light. Store the tablets in blisters in the provided box or carton.

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
3-A, Shiv Sagar Estate,
North Wing,

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

Dr. Annie Besant Road,
Worli, Mumbai 400 018
India
Tel: 91 22 6622 7575
Fax: 91 22 6622 7500/6622 7600

12. WHO Reference Number (Prequalification Programme)

MA193

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 on Alu blister

1. Name of the medicinal product

[MA193 trade name] Pyrimethamine/sulfadoxine 25 mg/500 mg
Pyrimethamine and sulfadoxine

2. Name of the supplier

S Kant Healthcare

3. Expiry date

EXP {MM/YY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE/bottle

6. Name of the medicinal product

[MA193 trade name] Pyrimethamine/sulfadoxine 25 mg/500 mg
Pyrimethamine and sulfadoxine

7. Statement of active substance

Each tablet contains Pyrimethamine 25 mg and sulfadoxine 500 mg

8. List of excipients

See patient information leaflet

9. Pharmaceutical form and contents

Tablets

1x 500

1x 1000

10. Method and route of administration

Oral use.

Read the patient information leaflet before use.

11. 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.

12. Other special warning(s), if necessary

13. Expiry date

EXP {MM/YYYY}

14. Special storage conditions

Avoid excursions above 30°C.

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

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