

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[MA191 trade name]* Pyrimethamine/sulfadoxine 12.5 mg/250 mg dispersible tablets

Pyrimethamine/sulfadoxine

2. Statement of active substance

Each dispersible tablet contains 12.5 mg pyrimethamine and 250 mg sulfadoxine

3. List of excipients

4. Pharmaceutical form and contents

Dispersible tablets

10 x 3 tablets

50 x 3 tablets

100 x 3 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 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. 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

Ipca Laboratories Limited
48, Kandivli Industrial Estate

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

Pyrimethamine/sulfadoxine
12.5 mg/250 mg dispersible tablets,
(Ipca Laboratories Ltd), MA191

WHOPAR Part 5

May 2024

Kandivli (W)
Mumbai 400 067
India

12. WHO Reference Number (Prequalification Programme)

MA191

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

PVC/Aluminium blisters

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Pyrimethamine/sulfadoxine

2. Name of the supplier

Ipca Laboratories Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other