LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Outer carton

1. Name of the medicinal product

[MA159 trade name]*

Pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets

2. Statement of active substance

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

3. List of excipients

Each tablet contains aspartame.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible tablets

1 x 3 tablets

10 x 3 tablets

25 x 3 tablets

50 x 3 tablets

100 x 3 tablets

10 x 10 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 reach and sight 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 tablets in the blisters in the provided carton.

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

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

Macleods Pharmaceuticals Limited

304, Atlanta Arcade,

Marol Church Road,

Andheri (East), Mumbai

400 059, India

12. WHO Reference Number (Prequalification Programme)

MA159

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
Clear PVC/PVDC-Alu blisters

1. **Name of the medicinal product**

   [MA159 trade name]

   Pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets

2. **Name of the supplier**

   Macleods Pharmaceuticals Limited

3. **Expiry date**

   EXP {MM/YYYY}

4. **Manufacturer's batch number**

   <Batch> <Lot>{number}

5. **Other**