LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. **Name of the medicinal product**

   [MA192 trade name]* Pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets

   Pyrimethamine/sulfadoxine

2. **Statement of active substance**

   Each dispersible tablet contains 25 mg pyrimethamine and 500 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

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

Kandivli (W)
Mumbai 400 067
India

12. WHO Reference Number (Prequalification Programme)

MA192

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

1. **Name of the medicinal product**

   [MA192 trade name] Pyrimethamine/sulfadoxine 25 mg/500 mg dispersible tablets

   Pyrimethamine/sulfadoxine

2. **Name of the supplier**

   Ipca Laboratories Limited

3. **Expiry date**

4. **Manufacturer's batch number**

   <Batch> <Lot>{number}

5. **Other**