LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Outer carton

1. Name of the medicinal product

[MA145 trade name]*

Sulfadoxine & pyrimethamine dispersible tablets 500/25 mg

2. Statement of active substance

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

3. List of excipients

Each tablet contains isomalt.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible tablets

1 × 3 tablets

10 × 3 tablets

25 × 3 tablets

50 × 3 tablets

10 × 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 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. Store tablets in blisters in the provided carton in order to protect from light.

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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

S Kant Healthcare Ltd
3-A Shiv Sagar Estate
North Wing
Dr Annie Besant Road
Worli, Mumbai 400 018
India

12. WHO Reference Number (Prequalification Programme)

MA145

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
Alu-PVC/PVDC blisters

1. **Name of the medicinal product**

   [MA145 trade name]

   Sulfadoxine & pyrimethamine dispersible tablets 500/25 mg

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**