LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product
[MA163 trade name][*] Pyrimethamine/Sulfadoxine 25 mg / 500 mg Dispersible Tablets

2. Statement of active substance
Each tablet contains pyrimethamine 25 mg and sulfadoxine 500 mg

3. List of excipients
The tablets also contain lactose monohydrate and orange flavour (which contains sugar [sucrose]).
See patient information leaflet for further information.

4. Pharmaceutical form and contents
Dispersible tablets

10 x 3 tablets
30 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 and moisture.

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
Universal Corporation Limited
Club Road, Plot No. 13777
P.O. Box 1748-00902
Kikuyu
Kenya

12. WHO Reference Number (Prequalification Programme)
MA163

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

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-Alu blister card

1. **Name of the medicinal product**
   [MA163 trade name] Pyrimethamine/Sulfadoxine 25mg/500mg dispersible tablets

2. **Name of the supplier**
   Universal Corporation Limited

3. **Expiry date**
   EXP {MM/YYYY}

4. **Manufacturer's batch number**
   <Batch> <Lot>{number}

5. **Other**