

## **LABELLING**

## PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

**1. Name of the medicinal product**

[MA166 trade name]\* Pyrimethamine/Sulfadoxine 12.5 mg / 250 mg Dispersible Tablets

**2. Statement of active substance**

Each tablet contains pyrimethamine 12.5 mg and sulfadoxine 250 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

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)**

MA166

---

\* 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**

[MA166 trade name] Pyrimethamine/Sulfadoxine 12.5mg/250mg 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**