

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

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)

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

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2. Name of the supplier

Universal Corporation Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other