

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[MA180 trade name]*

Pyrimethamine / sulfadoxine 25 mg / 500 mg tablets

2. Statement of active substance

Each tablet contains 25 mg of pyrimethamine and 500 mg of sulfadoxine.

3. List of excipients

Each tablet also contains about 31 mg of lactose monohydrate.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

1 x 3 tablets

10 x 3 tablets

50 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 out of the reach and sight of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {DD/MM/YYYY}

9. Special storage conditions

Do not store above 30°C. Avoid excursions above 30°C. Store 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

Swiss Pharma Nigeria Ltd

5, Dopemu Road,

Agege-Lagos

Ikeja 463

Nigeria

12. WHO Reference Number (Prequalification Programme)

MA180

* 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

(Swiss Pharma Nigeria Limited), MA180

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

PVC-Aluminium blister

1. Name of the medicinal product

[MA180 trade name]

Pyrimethamine / sulfadoxine 25 mg / 500 mg tablets

2. Name of the supplier

Swiss Pharma Nigeria Limited

3. Expiry date

EXP {DD/MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other