

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

- 1. Name of the medicinal product**
[HA598 trade name] * Sulfamethoxazole/trimethoprim 400mg/80mg tablets
- 2. Statement of active substance**
Each tablet contains 400 mg of sulfamethoxazole and 80 mg of trimethoprim.
- 3. List of excipients**
- 4. Pharmaceutical form and contents**
Tablets
10 x 10 tablets
50 x 10 tablets
100 x 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 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. Store in the original container.
- 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**
Micro Labs Limited
31, Race Course Road
Bangalore – 560001, Karnataka, India
- 12. WHO Reference Number (Prequalification Programme)**
HA598
- 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**

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

- 1. Name of the medicinal product**
[HA598 trade name] Sulfamethoxazole/trimethoprim 400mg/80mg tablets
Sulfamethoxazole & trimethoprim
- 2. Statement of active substance**
Each tablet contains 400 mg of sulfamethoxazole and 80 mg of trimethoprim.
- 3. List of excipients**
- 4. Pharmaceutical form and contents**
Tablets
100 tablets
500 tablets
1000 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. Store in the original container.
- 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**
Micro Labs Limited
31, Race Course Road
Bangalore – 560001, Karnataka, India
- 12. WHO Reference Number (Prequalification Programme)**
HA598
- 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-aluminium blister pack

1. Name of the medicinal product

[HA598 trade name] Sulfamethoxazole/trimethoprim 400mg/80mg tablets

2. Name of the supplier

Micro Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other