

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[HA599 trade name]* Sulfamethoxazole/trimethoprim 800mg/160mg tablets
Sulfamethoxazole/trimethoprim

2. Statement of active substance

Each tablet contains 800 mg of sulfamethoxazole and 160 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
Bengaluru – 560001, Karnataka, India

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
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12. WHO Reference Number (Prequalification Programme)

HA599

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[HA599 trade name][†] Sulfamethoxazole/trimethoprim 800mg/160mg tablets
Sulfamethoxazole/trimethoprim

2. Statement of active substance

Each tablet contains 800 mg of sulfamethoxazole and 160 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
Bengaluru – 560001, Karnataka, India

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

12. WHO Reference Number (Prequalification Programme)

HA599

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

[HA599 trade name] Sulfamethoxazole/trimethoprim 800mg/160mg tablets
Sulfamethoxazole/trimethoprim

2. Name of the supplier

Micro Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other