

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle label

1. Name of the medicinal product

[HA687 trade name]* Sulfamethoxazole/Trimethoprim 800 mg/160 mg tablets

Sulfamethoxazole/Trimethoprim

2. Statement of active substance

Each uncoated tablet contains 800 mg sulfamethoxazole and 160 mg trimethoprim.

3. List of excipients

4. Pharmaceutical form and contents

100 uncoated tablets

500 uncoated tablets

1000 uncoated 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

Mylan Laboratories Limited
Plot No. 564/A/22
Road No. 92, Jubilee Hills
Hyderabad-500096
Telangana

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

India
Email: ProductSafety@viatris.com

12. WHO Reference Number (Prequalification Programme)

HA687

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

Blister carton label

1. Name of the medicinal product

[HA687 trade name][†] Sulfamethoxazole/Trimethoprim 800 mg/160 mg tablets
Sulfamethoxazole/Trimethoprim

2. Statement of active substance

Each uncoated tablet contains 800 mg sulfamethoxazole and 160 mg trimethoprim.

3. List of excipients

4. Pharmaceutical form and contents

1 x 10 uncoated 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

Mylan Laboratories Limited
Plot No. 564/A/22
Road No. 92, Jubilee Hills
Hyderabad-500096
Telengana
India
Email: ProductSafety@viatris.com

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

12. WHO Reference Number (Prequalification Programme)

HA687

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

PVC/PVdC-Aluminium blister

1. Name of the medicinal product

[HA687 trade name] Sulfamethoxazole/Trimethoprim 800 mg/160 mg tablets

Sulfamethoxazole/Trimethoprim

2. Name of the supplier

Mylan Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch><Lot>{number}

5. Other