

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle label

1. Name of the medicinal product

[HA686 trade name]* Sulfamethoxazole/Trimethoprim 400 mg/80 mg tablets

Sulfamethoxazole/Trimethoprim

2. Statement of active substance

Each uncoated tablet contains 400 mg sulfamethoxazole and 80 mg trimethoprim.

3. List of excipients

4. Pharmaceutical form and contents

100 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
India

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

Email: ProductSafety@viatris.com

12. WHO Reference Number (Prequalification Programme)

HA686

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

[HA686 trade name][†] Sulfamethoxazole/Trimethoprim 400 mg/80 mg tablets

Sulfamethoxazole/Trimethoprim

2. Statement of active substance

Each uncoated tablet contains 400 mg sulfamethoxazole and 80 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)

HA686

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

[HA686 trade name] Sulfamethoxazole/Trimethoprim 400 mg/80 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