

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. Name of the medicinal product

[HA744 trade name]* Sulfamethoxazole/trimethoprim 400 mg/80 mg tablets
Sulfamethoxazole/trimethoprim

2. Statement of active substance

Each tablet contains sulfamethoxazole 400 mg and trimethoprim 80 mg.

3. List of excipients

Contains sodium benzoate

4. Pharmaceutical form and contents

Tablets

100 tablets

500 tablets

1000 tablets

5. Method and route of administration

Oral use.

Do not chew.

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. Avoid excursions above 30°C.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

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

11. Name and address of the supplier

Ipca Laboratories Limited
48, Kandivli Industrial Estate
Kandivli (W), Mumbai 400067
India.

12. Reference Number (Prequalification Programme)

HA744

13. Manufacturer's batch number

<Batch> {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

Carton blister label

1. Name of the medicinal product

[HA744 trade name] Sulfamethoxazole/trimethoprim 400 mg/80 mg tablets
Sulfamethoxazole/trimethoprim

2. Statement of active substance

Each tablet contains sulfamethoxazole 400 mg and trimethoprim 80 mg.

3. List of excipients

Contains sodium benzoate

4. Pharmaceutical form and contents

Tablets
10×10 tablets

5. Method and route of administration

Oral use.
Do not chew.
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. Avoid excursions above 30°C.

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

Ipca Laboratories Limited
48, Kandivli Industrial Estate
Kandivli (W), Mumbai 400067
India.

12. Reference Number (Prequalification Programme)

HA744

13. Manufacturer's batch number

<Batch> {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
PVdC/PVC-Aluminium Blister label

1. Name of the medicinal product

[HA744 trade name] Sulfamethoxazole/trimethoprim 400 mg/80 mg tablets
Sulfamethoxazole/trimethoprim

2. Name of the supplier

Ipca Laboratories Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch>-{number}

5. Other