

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle label

1. Name of the medicinal product

[HA774 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

Contains lactose

4. Pharmaceutical form and contents

100 Tablets

500 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

Store at or below 30°C. Keep the bottle HDPE bottle pack tightly closed to protect from moisture.

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

Shouguang Fukang Pharmaceutical Company Limited
No. 666 Donghuan Road
Shouguang City
Shandong 262700
China

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

12. WHO Reference Number (Prequalification Programme)

HA774

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

[HA774 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

Contains lactose

4. Pharmaceutical form and contents

25 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

Store at or below 30°C. Store tablets in the blisters in the provided carton to protect from moisture and light.

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

Shouguang Fukang Pharmaceutical Company Limited
No. 666 Donghuan Road
Shouguang City
Shandong 262700
China

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

12. WHO Reference Number (Prequalification Programme)

HA774

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/Aluminium blisters

1. Name of the medicinal product

[HA774 trade name] Sulfamethoxazole/trimethoprim 400 mg/80 mg tablets

Sulfamethoxazole/trimethoprim

2. Name of the supplier

Shouguang Fukang Pharmaceutical Company Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other