

Isoniazid/Pyridoxine hydrochloride/
Sulfamethoxazole/Trimethoprim
300mg/25mg/800mg/160mg tablets
(Mylan Laboratories Ltd), HA762

WHOPAR Part 5

September 2022

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE Bottle

1. Name of the medicinal product

[HA762 trade name]* Isoniazid/Pyridoxine hydrochloride/ Sulfamethoxazole/Trimethoprim
300 mg / 25 mg / 800 mg /160 mg tablets

2. Statement of active substance

Each tablet contains isoniazid 300 mg, pyridoxine hydrochloride 25 mg, sulfamethoxazole 800 mg and trimethoprim 160 mg.

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets
30 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

12. WHO Reference Number (Prequalification Programme)

HA762

13. Manufacturer's batch number

<Batch> <Lot> {number}

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

Isoniazid/Pyridoxine hydrochloride/
Sulfamethoxazole/Trimethoprim
300mg/25mg/800mg/160mg tablets
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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

1. Name of the medicinal product

[HA762 trade name] Isoniazid/Pyridoxine hydrochloride/ Sulfamethoxazole/Trimethoprim
300 mg / 25 mg / 800 mg /160 mg tablets

2. Statement of active substance

Each tablet contains isoniazid 300 mg, pyridoxine hydrochloride 25 mg, sulfamethoxazole 800mg and trimethoprim 160 mg.

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets
10 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

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

12. WHO Reference Number (Prequalification Programme)

HA762

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

Alu-OPA/PVC/Alu blister card

1. Name of the medicinal product

[HA762 trade name] Isoniazid/Pyridoxine hydrochloride/ Sulfamethoxazole/Trimethoprim
300 mg / 25 mg / 800 mg / 160 mg tablets

2. Name of the supplier

Mylan Laboratories Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other