

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB015 trade name]* Pyrazinamide 400 mg Tablets

2. Statement of active substance

Each tablet contains 400 mg pyrazinamide.

3. List of excipients

The tablets also contain methyl paraben.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablet
10 x 10 tablets
24 x 28 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.

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

Cadila Pharmaceuticals Limited
1389 Trasad Road, Dholka – 382 225,
Ahmedabad, Gujarat, India

12. WHO Reference Number (Prequalification Programme)

TB015

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

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB015 trade name] Pyrazinamide 400 mg Tablets

2. Statement of active substance

Each tablet contains 400 mg pyrazinamide.

3. List of excipients

The tablets also contain methyl paraben.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets
1000 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.

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

Cadila Pharmaceuticals Limited
1389 Trasad Road
Dholka – 382 225
Ahmedabad, Gujarat, India

12. WHO Reference Number (Prequalification Programme)

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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

PVC/PVdC-aluminium blister, PVC - aluminium blister.

1. Name of the medicinal product

[TB015 trade name] Pyrazinamide 400 mg Tablets

2. Name of the supplier

Cadila Pharmaceuticals Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other