

LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING
HDPE Bottle Label**

1. Name of the medicinal product

[TB171 trade name]¹ Pyrazinamide 400 mg tablets
Pyrazinamide

2. Statement of active substance

Each tablet contains 400 mg of pyrazinamide

3. List of excipients

Contains lactose. See patient information leaflet for further information

4. Pharmaceutical form and contents

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 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

Micro Labs Limited
31 Race Course Road
Bangalore 560 001
Karnataka

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

India

Tel : +91-80-22370451-54

Fax: +91-80-22370463

12. WHO Reference Number (Prequalification Programme)

TB171

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 label for blister pack

1. Name of the medicinal product

[TB171 trade name]² Pyrazinamide 400 mg tablets

Pyrazinamide

2. Statement of active substance

Each tablet contains 400 mg of pyrazinamide

3. List of excipients

Contains lactose. See patient information leaflet for further information

4. Pharmaceutical form and contents

24 x 28 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 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

Micro Labs Limited
31 Race Course Road
Bangalore 560 001

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12. WHO Reference Number (Prequalification Programme)

TB171

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 STRIPS

1. Name of the medicinal product

[TB171 trade name]³ Pyrazinamide 400 mg tablets
Pyrazinamide

2. Name of the supplier

Micro Labs Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}

³ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.