

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Container

1. Name of the medicinal product

[TB335 trade name]* Pyrazinamide 150 mg Dispersible Tablets

Pyrazinamide

2. Statement of active substance

Each tablet contains 150 mg pyrazinamide

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible tablets

100 tablets

500 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 out of the reach and sight 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. Protect from moisture. Store in the original pack.

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

Micro Labs Limited
31, Race Course Road
Bangalore – 560001
Karnataka
India
Tel: +91-80-2237 0451 to 2237 0454
Fax: +91-80-2237 0463

12. WHO Reference Number (Prequalification Programme)

TB335

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

Carton

1. Name of the medicinal product

[TB335 trade name][†] Pyrazinamide 150 mg Dispersible Tablets

Pyrazinamide

2. Statement of active substance

Each tablet contains 150 mg pyrazinamide

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible 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 reach and sight 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. Protect from moisture. Store in the original pack.

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.

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<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

Aluminium Strip

1. Name of the medicinal product

[TB335 trade name] Pyrazinamide 150 mg Dispersible Tablets

Pyrazinamide

2. Name of the supplier

Micro Labs Ltd

3. Expiry date

EXP {MM YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other