

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

- 1. Name of the medicinal product**
[TB172 trade name]* Pyrazinamide 500 mg Tablets
Pyrazinamide
- 2. Statement of active substance**
Each tablet contains 500 mg pyrazinamide.
- 3. List of excipients**
- 4. Pharmaceutical form and contents**
1 000 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**
Micro Labs Limited
#31, Race Course Road
Bangalore 560 001
Karnataka, India
- 12. WHO Reference Number (Prequalification Programme)**
TB172
- 13. Manufacturer's batch number**
<Batch> <Lot> {number}
- 14. (Advice on) General classification for supply**
Medicinal product subject to medical prescription.

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

15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[TB172 trade name] Pyrazinamide 500 mg Tablets
Pyrazinamide

2. Statement of active substance

Each tablet contains 500 mg pyrazinamide.

3. List of excipients

4. Pharmaceutical form and contents

Tablets
9 x 10 tablets
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

Micro Labs Limited
#31, Race Course Road
Bangalore 560 001
Karnataka
India

12. WHO Reference Number (Prequalification Programme)

TB172

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 blister

- 1. Name of the medicinal product**
[TB172 trade name] Pyrazinamide 500 mg Tablets
- 2. Name of the supplier**
Micro Labs Limited
- 3. Expiry date**
EXP {MM/YYYY}
- 4. Manufacturer's batch number**
<Batch> <Lot>{number}
- 5. Other**