

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. Name of the medicinal product

[TB159 trade name] * Pyrazinamide 400 mg Tablets
Pyrazinamide

2. Statement of active substance

Each tablet contains 400 mg pyrazinamide.

3. List of excipients

4. Pharmaceutical form and contents

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 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. Protect from moisture.

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

Macleods Pharmaceuticals Ltd
304, Atlanta Arcade
Marol Church Road
Andheri (East), Mumbai- 400 059
India

12. WHO Reference Number (Prequalification Programme)

TB159

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

[TB159 trade name] Pyrazinamide 400 mg Tablets
Pyrazinamide

2. Statement of active substance

Each tablet contains 400 mg pyrazinamide.

3. List of excipients

4. Pharmaceutical form and contents

Tablets

3 x 10 tablets

3 x 28 tablets

10 x 10 tablets

24 x 10 tablets

10 x 28 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. Protect from moisture.

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

Macleods Pharmaceuticals Ltd

304, Atlanta Arcade

Marol Church Road

Andheri (East), Mumbai- 400 059

India

12. WHO Reference Number (Prequalification Programme)

TB159

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/PVC or Alu/PVDC silver-coated PVC blisters

1. Name of the medicinal product

[TB159 trade name] Pyrazinamide 400 mg Tablets
Pyrazinamide

2. Name of the supplier

Macleods Pharmaceuticals Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other