

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle

1. Name of the medicinal product

[TB243 trade name]*

Pyrazinamide 500 mg tablets

2. Statement of active substance

Each tablet contains 500 mg pyrazinamide

3. List of excipients

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. 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 Limited

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

304, Atlanta Arcade,
Marol Church road,
Andheri (East),
Mumbai – 400 059, INDIA.
Tel: +91-22-66762800
Fax: +91 -22-28216599

12. WHO Reference Number (Prequalification Programme)

TB243

13. Manufacturer's batch number

<Batch><Lot> {number}

14. General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[TB243 trade name][†]

Pyrazinamide 500 mg tablets

2. Statement of active substance

Each tablet contains 500 mg pyrazinamide

3. List of excipients

4. Pharmaceutical form and contents

Tablets

3 x 10 tablets

10 x 10 tablets

10 x 7 tablets

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

3 x 28 tablets

24 x 28 tablets

9x10 tablets

24x10 tablets

10x28 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

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12. WHO Reference Number (Prequalification Programme)

TB243

13. Manufacturer's batch number

<Batch><Lot> {number}

14. General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blister

1. Name of the medicinal product

[TB243 trade name]

Pyrazinamide 500 mg tablets

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch><Lot>{number}

5. Other