

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle/Carton

1. Name of the medicinal product

[TB183 trade name]* Ethambutol hydrochloride 275 mg, isoniazid 75 mg and rifampicin 150 mg tablets

Ethambutol hydrochloride/isoniazid/rifampicin.

2. Statement of active substance

Each tablet contains Ethambutol hydrochloride 275 mg, isoniazid 75 mg and rifampicin 150 mg

3. List of excipients

See patient information leaflet

4. Pharmaceutical form and contents

Film coated tablets

1x1000's
(HDPE bottle)

3x10's

10x10's

24x10's

3x28's

10x28's

24x28's

5x6's

5. Method and route of administration

Oral use.

Do not chew.

Read the patient information leaflet before use.

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

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

For [TB183 trade name] packaged in cartons are applied as follows:

- For Blister Pack: Store in a dry place below 25°C and protect from light.
- For Strip pack: Store in a dry place below 30°C and protect from light.

For [TB183 trade name] in bulk HDPE packs: Store at temperature not exceeding 25°C in a dry place.

Tablets should be stored in the original container. Close the container tightly immediately after taking out tablets.

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
304, Atlanta Arcade
Marol Church Road
Andheri (East)
400 059 Mumbai
India

12. WHO Reference Number (Prequalification Programme)

TB183

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

Al/PVC/PE/PVDC blister, Al/PVC/PVDC-Alu blister and Alu-Alu strip

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5. Other