LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB388 trade name][*]

Delamanid 50 mg tablets

2. Statement of active substance

Each film-coated tablet contains 50 mg delamanid.

3. List of excipients

Each tablet contains lactose.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets.

6 x 8 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. Store in the original package in order to protect from moisture.

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

Mylan Laboratories Limited

Plot No. 564/A/22, Road No. 92

Jubilee Hills

Hyderabad - 500096

Telangana, India

12. WHO Reference Number (Prequalification Programme)

TB388

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 /Alu blister

1. Name of the medicinal product

[TB388 trade name]

Delamanid 50 mg tablets

2. Name of the supplier

Mylan Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other