

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB408 trade name]* Bedaquiline (as fumarate) 100 mg tablets
Bedaquiline

2. Statement of active substance

Each tablet contains bedaquiline fumarate equivalent to 100 mg bedaquiline.

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Tablets

4 x 6 tablets

10 x10 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 container. Avoid excursions above 30°C.

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)

TB408

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
HDPE

1. Name of the medicinal product

[TB408 trade name] Bedaquiline (as fumarate) 100 mg tablets
Bedaquiline

2. Statement of active substance

Each tablet contains bedaquiline fumarate equivalent to 100 mg bedaquiline.

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Tablets
188 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 container. Avoid excursions above 30°C.
Discard the product 180 days after initial opening.

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

Mylan Laboratories Limited
Plot No.564/A/22, Road No. 92, Jubilee Hills
Hyderabad – 500096
Telangana
India

12. WHO Reference Number (Prequalification Programme)

TB408

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

Alu/Alu blister cards

1. Name of the medicinal product

[TB408 trade name] Bedaquiline (as fumarate) 100 mg tablets
Bedaquiline

2. Name of the supplier

Mylan Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other