

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Plastic (HDPE) bottle

1. Name of the medicinal product

[TB396 trade name]* Bedaquiline (as fumarate) 100mg tablets
Bedaquiline

2. Statement of active substance

Each tablet contains 120.89 mg bedaquiline fumarate equivalent to 100 mg bedaquiline.

3. List of excipients

Each tablet also contains lactose.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets
24 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 or package to protect from light. Avoid excursions above 30°C.

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

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East), Mumbai 400055
India

12. WHO Reference Number (Prequalification Programme)

TB396

13. Manufacturer's batch number

<Batch> <Lot> {number}

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

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister / strip pack carton

1. Name of the medicinal product

[TB396 trade name] Bedaquiline (as fumarate) 100mg tablets
Bedaquiline

2. Statement of active substance

Each tablet contains 120.89 mg bedaquiline fumarate equivalent to 100 mg bedaquiline.

3. List of excipients

Each tablet also contains lactose.
See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

Blisters

08 x 12 tablets

11 x 12 tablets

04 x 14 tablets

Strips

10 x 10 tablets

04 x 14 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 or package to protect from light. Avoid excursions above 30°C.

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

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East), Mumbai 400055
India

12. WHO Reference Number (Prequalification Programme)

TB396

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

Aluminium blisters/strips

- 1. Name of the medicinal product**
[TB396 trade name] Bedaquiline (as fumarate) 100mg tablets
Bedaquiline
- 2. Name of the supplier**
Lupin Ltd
- 3. Expiry date**
EXP {MM/YYYY}
- 4. Manufacturer's batch number**
<Batch> <Lot>{number}
- 5. Other**