

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB390 trade name]* Bedaquiline (as fumarate) 100 mg tablets
Bedaquiline

2. Statement of active substance

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

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Uncoated tablet
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. Avoid excursions above 30°C. Store in the original container or package to protect from light.

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

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

12. WHO Reference Number (Prequalification Programme)

TB390

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 OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB390 trade name][†] Bedaquiline (as fumarate) 100 mg tablets
Bedaquiline

2. Statement of active substance

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

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Uncoated tablet

12 x 6 tablets

10 x 10 tablets

7 x 28 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. Avoid excursions above 30°C. Store in the original container or package to protect from light.

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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church Road
Andheri (East)
Mumbai – 400 059
India

12. WHO Reference Number (Prequalification Programme)

TB390

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 blisters

1. Name of the medicinal product

[TB390 trade name] Bedaquiline (as fumarate) 100 mg name tablets
Bedaquiline

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other