

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[TB395 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 monohydrate

4. Pharmaceutical form and contents

Tablets

4 x 6 tablets

1 x 10 tablets

3 x 10 tablets

10 x 10 tablets.

5. Method and route of administration

Oral use.

Do not chew.

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 tablets in the original container to protect from light.

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

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

MSN Laboratories Private Limited
“MSN House”, Plot No: C – 24
Industrial Estate, Sanath Nagar
Hyderabad – 500 018, Telangana
India

12. WHO Reference Number (Prequalification Programme)

TB395

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 bottle

1. Name of the medicinal product

[TB395 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 monohydrate

4. Pharmaceutical form and contents

Tablets

188 tablets

5. Method and route of administration

Oral use.

Do not chew.

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 tablets in the original container to protect from light.

Discard the product 90 days after initial opening.

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

MSN Laboratories Private Limited
“MSN House”, Plot No: C – 24,
Industrial Estate, Sanath Nagar,
Hyderabad – 500 018, Telangana, India

12. WHO Reference Number (Prequalification Programme)

TB395

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

Blister

1. Name of the medicinal product

[TB395 trade name] * Bedaquiline (as fumarate) 100 mg tablets

Bedaquiline

2. Name of the supplier

MSN Laboratories Private Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other