

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE container

1. Name of the medicinal product

[TB361 trade name]* Clofazimine 50 mg tablets
Clofazimine

2. Statement of active substance

Each film-coated tablet contains 50 mg clofazimine.

3. List of excipients

Contains castor oil polyoxyl hydrogenated and betadex.

4. Pharmaceutical form and contents

Film-coated tablet
100 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. 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

Macleods Pharmaceuticals Limited
Atlanta Arcade

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

Marol Church road
Andheri (East)
Mumbai – 400 059
INDIA

12. WHO Reference Number (Prequalification Programme)

TB361

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

Blister pack

1. Name of the medicinal product

[TB361 trade name] Clofazimine 50 mg tablets
Clofazimine

2. Statement of active substance

Each film-coated tablet contains 50 mg clofazimine.

3. List of excipients

Contains castor oil polyoxyl hydrogenated and betadex.

4. Pharmaceutical form and contents

Film-coated tablet
10x10 tablets
10x28 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. 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

Macleods Pharmaceuticals Limited
Atlanta Arcade

Marol Church road
Andheri (East)
Mumbai – 400 059
INDIA

12. WHO Reference Number (Prequalification Programme)

TB361

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

Strip pack

1. Name of the medicinal product

[TB361 trade name] Clofazimine 50 mg tablets
Clofazimine

2. Statement of active substance

Each film-coated tablet contains 50 mg clofazimine.

3. List of excipients

Contains castor oil polyoxyl hydrogenated and betadex.

4. Pharmaceutical form and contents

Film-coated tablet
10x10 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. 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

Macleods Pharmaceuticals Limited
Atlanta Arcade
Marol Church road

Andheri (East)
Mumbai – 400 059
INDIA

12. WHO Reference Number (Prequalification Programme)

TB361

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

PVC/PVDC-aluminium blister and polyethene film strip

1. Name of the medicinal product

[TB361 trade name] Clofazimine 50 mg tablets

Clofazimine

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other