

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE container

1. Name of the medicinal product

[TB362 trade name]*

clofazimine 100 mg tablets

2. Statement of active substance

Each film-coated tablet contains 100 mg clofazimine.

3. List of excipients

Contains castor oil polyoxyl hydrogenated and betadex.

See the patient information leaflet for further information.

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 out of the reach and sight 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

* 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)

TB362

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

16. Name of the medicinal product

[TB362 trade name]

clofazimine 100 mg tablets

17. Statement of active substance

Each film-coated tablet contains 100 mg clofazimine.

18. List of excipients

Contains castor oil polyoxyl hydrogenated and betadex.

See the patient information leaflet for further information.

19. Pharmaceutical form and contents

Film-coated tablet

10x10 tablets

10x28 tablets

20. Method and route of administration

Oral use.

Read the patient information leaflet before use.

21. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

22. Other special warning(s), if necessary

23. Expiry date

EXP {MM/YYYY}

24. Special storage conditions

Do not store above 30°C. Protect from light. Avoid excursions above 30°C.

25. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

26. Name and address of the supplier

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

27. WHO Reference Number (Prequalification Programme)

TB362

28. Manufacturer's batch number

<Batch> <Lot> {number}

29. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

30. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Strip pack

31. Name of the medicinal product

[TB362 trade name]

clofazimine 100 mg tablets

32. Statement of active substance

Each film-coated tablet contains 100 mg clofazimine.

33. List of excipients

Contains castor oil polyoxyl hydrogenated and betadex.

See the patient information leaflet for further information.

34. Pharmaceutical form and contents

Film-coated tablet

8x6 tablets

10x10 tablets

35. Method and route of administration

Oral use.

Read the patient information leaflet before use.

36. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep out of the reach and sight of children.

37. Other special warning(s), if necessary

38. Expiry date

EXP {MM/YYYY}

39. Special storage conditions

Do not store above 30°C. Protect from light. Avoid excursions above 30°C.

40. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

41. Name and address of the supplier

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

42. WHO Reference Number (Prequalification Programme)

TB362

43. Manufacturer's batch number

<Batch> <Lot> {number}

44. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

45. 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

[TB362 trade name]

clofazimine 100 mg tablets

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other