

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB364 trade name]* Clofazimine 100 mg soft capsules

Clofazimine

2. Statement of active substance

Each soft capsule contains 100 mg clofazimine

3. List of excipients

Each capsule contains soybean oil, glycerin, methylparaben and propylparaben.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Soft capsule

100 capsules

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.

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

Dong-A ST Co. Ltd.
64, Cheonho-daero
Dongdaemun-gu
Seoul 130 708
Republic of Korea

12. WHO Reference Number (Prequalification Programme)

TB364

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