

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. Name of the medicinal product

[NT005 trade name]* Albendazole 400 mg tablets

Albendazole

2. Statement of active substance

Each tablet contains 400 mg albendazole

3. List of excipients

Each tablet contains about 569.6 mg of lactose monohydrate and 3 mg of colour FD & C yellow #6 (Lake sunset yellow FCF).

See patient information leaflet for further information

4. Pharmaceutical form and contents

Tablets

60 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. Discard the product 30 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

Cipla Limited
Cipla House
Peninsula Business park
Ganpatrao Kadam Marg
Lower Parel
Mumbai 400 013
India

12. WHO Reference Number (Prequalification Programme)

NT005

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