

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[NT016 trade name]* Albendazole 400 mg Chewable Tablets
Albendazole

2. Statement of active substance

Each chewable tablet contains 400 mg of albendazole.

3. List of excipients

Each tablet also contains lactose monohydrate, sunset yellow/FD&C yellow #6, sodium benzoate, benzyl alcohol.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Chewable tablets

4 x 14 tablets

6 x 10 tablets

10 x 10 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 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. Avoid excursions above 30°C. Protect from light.

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

Indoco Remedies Limited
166, C.S.T. Road
Mumbai 400 098, India

12. WHO Reference Number (Prequalification Programme)

NT016

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-Alu and Alu/Alu blisters

1. Name of the medicinal product

[NT016 trade name]

Albendazole 400 mg chewable tablets

2. Name of the supplier

Indoco Remedies Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other