

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton or HDPE bottle

1. Name of the medicinal product

[N021 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 66.5 mg of lactose as lactose monohydrate

4. Pharmaceutical form and contents

Tablets

1x10's blisters

1x60's HDPE bottle

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

Store below 30°C. Avoid excursions above 30°C.

Discard the product 30 days after initial opening. (*Applicable to HDPE bottles*)

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

Ipca Laboratories Limited
48, Kandivli Industrial Estate
Kandivli (W), Mumbai 400 067
India

12. WHO Reference Number (Prequalification Programme)

NT021

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

PVDC/PVC aluminium blister card

1. Name of the medicinal product

[N021 trade name] Albendazole 400 mg tablets

Albendazole

2. Name of the supplier

Ipca Laboratories Limited

3. Expiry date

EXP MM/YYYY

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other