

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton for blister

1. Name of the medicinal product

[NT017 trade name]* Miltefosine 50mg capsules
Miltefosine

2. Statement of active substance

Each hard capsule contains 50mg miltefosine.

3. List of excipients

Contains lactose.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Hard capsule

10 x 10 hard 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. Protect from moisture.

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

Zydus Lifesciences Limited
“Zydus Corporate Park”
Scheme no. 63, survey no. 536,
Khoraj (Gandhinagar), Near. Vaishnodevi Circle,
Ahmedabad, Gujarat
India – 382481
E-mail; Drugsafety@zyduslife.com

12. WHO Reference Number (Prequalification Programme)

NT017

13. Manufacturer’s batch number

<Batch>{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

Alu/Alu foil blister

1. Name of the medicinal product

[NT017 trade name] Miltefosine 50mg capsules

Miltefosine

2. Name of the supplier

Zydus Lifesciences Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

Batch{number}

5. Other