

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[NT007 trade name]* Ivermectin 3 mg Tablets

2. Statement of active substance

Each tablet contains 3 mg of ivermectin

3. List of excipients

4. Pharmaceutical form and contents

Tablets

1 x 1 tablet

1 x 10 tablets

250 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. Keep the container tightly closed in order to protect from light.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

11. Name and address of the supplier

Laboratorios Liconsa
C/ Dulcinea s/n
28805 Alcalá de Henares
Madrid
Spain

* Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

12. WHO Reference Number (Prequalification Programme)

[NT007 trade name]

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 THE IMMEDIATE PACKAGING
HDPE Bottle**

- 1. Name of the medicinal product**
[NT007 trade name]
Ivermectin 3mg Tablets
- 2. Method of administration**
Oral use.
- 3. Expiry date**
EXP {MM/YYYY}
- 4. Manufacturer's batch number**
<Batch> <Lot>{number}
- 5. Contents by weight, by volume or by unit**
250 tablets
- 6. Name and address of the supplier**
Laboratorios Liconsa
C/ Dulcinea s/n
28805 Alcalá de Henares
Madrid, Spain
- 7. Directions for use and any warnings or precautions that may be necessary**

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blister

- 1. Name of the medicinal product**
[NT007 trade name]
Ivermectin 3mg Tablets
- 2. Name of the supplier**
Laboratorios Liconsa S.A.
- 3. Expiry date**
EXP {MM/YYYY}
- 4. Manufacturer's batch number**
<Batch> <Lot>{number}
- 5. Other**