

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton (Blister)

1. Name of the medicinal product

[NT007 trade name]* Ivermectin 3 mg tablets

Ivermectin

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

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. Avoid excursions above 30°C.

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

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

12. WHO Reference Number (Prequalification Programme)

NT007

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton of HDPE

1. Name of the medicinal product

[NT007 trade name][†] Ivermectin 3 mg tablets
Ivermectin

2. Statement of active substance

Each tablet contains 3 mg of ivermectin

3. List of excipients

4. Pharmaceutical form and contents

Tablets
250 mg 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 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. Avoid excursions above 30°C. Keep the HDPE bottle 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

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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

12. WHO Reference Number (Prequalification Programme)

NT007

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE Bottle

1. Name of the medicinal product

[NT007 trade name][‡] Ivermectin 3 mg tablets
Ivermectin

2. Statement of active substance

Each tablet contains 3 mg of ivermectin

3. List of excipients

4. Pharmaceutical form and contents

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 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. Avoid excursions above 30°C. Keep the HDPE bottle 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

[‡] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

11. Name and address of the supplier

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

12. WHO Reference Number (Prequalification Programme)

NT007

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

Blister

1. Name of the medicinal product

[NT007 trade name] Ivermectin 3 mg tablets

Ivermectin

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