

LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING
HDPE Bottle Label**

1. Name of the medicinal product

[NT011 trade name]¹ Praziquantel 600 mg tablets
Praziquantel

2. Statement of active substance

Each tablet contains 600 mg of praziquantel

3. List of excipients

See patient information leaflet for further information

4. Pharmaceutical form and contents

6 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 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. Store in the original container.

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

Hetero Labs Limited
Hetero Corporate
7-2-A2, Industrial Estates
Sanath Nagar

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Hyderabad
Telangana, 500 018
India

Tel : +91 40 23704923/ 24/25/26 /27/28
+91 40 23707171 / 7272 / 7744
Fax : +91 40 23714250 / 2370 4926

12. WHO Reference Number (Prequalification Programme)

NT011

13. Manufacturer's batch number

<Batch> {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

HDPE Bottle Label

1. Name of the medicinal product

[NT011 trade name]² Praziquantel 600 mg tablets

Praziquantel

2. Statement of active substance

Each tablet contains 600 mg of praziquantel

3. List of excipients

See patient information leaflet for further information

4. Pharmaceutical form and contents

100 tablets

500 tablets

1000 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 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. Store in the original container.

Discard the product 180 days after initial opening.

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

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11. Name and address of the supplier

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15. Instructions on use

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label for blister pack

1. Name of the medicinal product

[NT011 trade name]³ Praziquantel 600 mg tablets

Praziquantel

2. Statement of active substance

Each tablet contains 600 mg of praziquantel

3. List of excipients

See patient information leaflet for further information

4. Pharmaceutical form and contents

1 x 6 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 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. Store in the original container.

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

Hetero Labs Limited

Hetero Corporate

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12. WHO Reference Number (Prequalification Programme)

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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 STRIPS

1. Name of the medicinal product

[NT011 trade name]⁴ Praziquantel 600 mg tablets

Praziquantel

2. Name of the supplier

Hetero Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}

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