

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle label

1. Name of the medicinal product

[NT011 trade name]* 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

Tablet

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 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. Store in the original container.

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

Hetero Labs Limited
Hetero Corporate
7-2-A2, Industrial Estates
Sanath Nagar
Hyderabad
Telangana, 500 018
India
Tel: +91 40 23704923

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][†] 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

Tablet

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 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. Store in the original container.

Discard the product 180 days after initial opening.

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

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

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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][‡] 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

Tablets

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 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. Store in the original container.

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

Hetero Labs Limited
Hetero Corporate
7-2-A2, Industrial Estates
Sanath Nagar
Hyderabad
Telangana, 500 018
India
Tel: +91 40 23704923

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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Carton label for blister pack

1. Name of the medicinal product

[NT011 trade name] 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}

5. Other