

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[NT022 trade name]* Praziquantel 600 mg film-coated tablets

Praziquantel

2. Statement of active substance

Each film-coated tablet contains 600 mg praziquantel

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablet

10 x 10 tablets

5. Method and route of administration

Oral use.

Do not chew.

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.

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

Mepro Pharmaceuticals Pvt. Ltd.
3rd Floor, The International building
16, Maharshi Karve Road, Church gate
Mumbai, Maharashtra 400 020
India

12. WHO Reference Number (Prequalification Programme)

NT022

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

1. Name of the medicinal product

[NT022 trade name][†] Praziquantel 600 mg film-coated tablets

Praziquantel

2. Statement of active substance

Each film-coated tablet contains 600 mg praziquantel

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablet

100 tablets

500 tablets

5. Method and route of administration

Oral use.

Do not chew.

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.

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

Mepro Pharmaceuticals Pvt. Ltd.
3rd Floor, The International building,
16, Maharshi Karve Road, Church gate,
Mumbai, Maharashtra 400 020
India

12. WHO Reference Number (Prequalification Programme)

NT022

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

PVDC/PVC/aluminium foil blister

1. Name of the medicinal product

[NT022 trade name] Praziquantel 600 mg film-coated tablets
Praziquantel

2. Name of the supplier

Mepro Pharmaceuticals Pvt. Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other