

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle label

1. Name of the medicinal product

[NT013 trade name]* Praziquantel 600 mg tablets

Praziquantel

2. Statement of active substance

Each film-coated tablet contains 600 mg praziquantel

3. Pharmaceutical form and contents

Film-coated tablets

1000 tablets

4. Method and route of administration

Oral use

Read the patient information leaflet before use.

5. 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.

6. Other special warning(s), if necessary

7. Expiry date

EXP {MM/YYYY}

8. Special storage conditions

Do not store above 30°C. Avoid excursions above 30°C. Protect from light and humidity. Discard the product 180 days after initial opening.

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

10. Name and address of the supplier

Merck Healthcare KGaA

Frankfurter Street 250

64293 Darmstadt

Germany

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

11. Name and address of the manufacturer

Merck S. A. de C.V.
Calle 5, No. 7
Fraccionamiento Industrial Alce Blanco
Naucalpan de Juárez
C.P. 53370
Mexico

12. WHO Reference Number (Prequalification Programme)

NT013

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