

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[TB353 trade name]*

Protonamide 250 mg tablets

2. Statement of active substance

Each film-coated tablet contains protonamide 250 mg

3. List of excipients

Each film-coated tablet contains about 20.9 mg of lactose monohydrate

See patient information leaflet for further information

4. Pharmaceutical form and contents

Film-coated tablet

5 x 10 tablets

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. Store tablets in blisters in the provided carton to protect from light.

* 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

11. Name and address of the supplier

LEKHIM Joint Stock Company
23, Shota Rustaveli Street
Kyiv, 01033
Ukraine

12. WHO Reference Number (Prequalification Programme)

TB353

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

PVC-aluminium blister

1. Name of the medicinal product

[TB353 trade name]

Protionamide 250 mg tablets

2. Name of the supplier

LEKHIM Joint Stock Company

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch>{number}

5. Other