

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB206 trade name]* Protonamide 250 mg film-coated tablets

Protonamide

2. Statement of active substance

Each film-coated tablet contains 250mg protonamide.

3. List of excipients

Contains sodium benzoate and propylene glycol

4. Pharmaceutical form and contents

Film-coated tablets

50 film-coated 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. Protect from light.

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

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East)
Mumbai 400055

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

India

12. WHO Reference Number (Prequalification Programme)

TB206

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 OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[TB206 trade name][†] Protonamide 250 mg film-coated tablets
Protonamide

2. Statement of active substance

Each film-coated tablet contains 250mg protonamide.

3. List of excipients

Contains sodium benzoate and propylene glycol

4. Pharmaceutical form and contents

Film-coated tablets
100 (10x10) film-coated tablets
280 (28x10) film-coated 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. Protect from light.
Store tablets in blisters in the provided carton.

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

Lupin Limited
Kalpataru Inspire

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<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

Alu/PVC/PVdC , Alu/PVC/PE/PVdC, Alu/PVC/Aclar blisters

1. Name of the medicinal product

[TB206 trade name] Protonamide 250 mg film-coated tablets

Protonamide

2. Name of the supplier

Lupin Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other