

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[TB239 trade name]*

Protionamide 250 mg tablets

2. Statement of active substance

Each film-coated contains protionamide 250 mg

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

140 (14 x10) film-coated tablets

100 (10 x 10) film-coated 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. 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

Micro Labs Limited

31, Race Course Road

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

Bangalore 560 001
Karnataka
India

12. WHO Reference Number (Prequalification Programme)

TB239

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

HDPE Bottle

1. Name of the medicinal product

[TB239 trade name][†]

Protionamide 250 mg tablets

2. Statement of active substance

Each film-coated contains protionamide 250 mg

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

100 film-coated 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. 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

Micro Labs Limited

31, Race Course Road

Bangalore 560 001

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Karnataka

India

12. WHO Reference Number (Prequalification Programme)

TB239

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 OR STRIP

Blister strip

1. Name of the medicinal product

[TB239 trade name]

Protionamide 250 mg tablets

2. Name of the supplier

Micro Labs Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other