

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE Bottle

1. Name of the medicinal product

[TB383 trade name]*

Pyridoxine hydrochloride 50 mg tablets

2. Statement of active substance

Each tablet contains 50 mg of pyridoxine hydrochloride.

3. List of excipients

4. Pharmaceutical form and contents

Tablets

1000 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

Keep this medicine out of the sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

Should be used within 90 days, once opened. Date of opening {D D / M M / Y Y}

9. Special storage conditions

Store in a dry place below 30°C, protected 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

Macleods Pharmaceuticals Ltd

304, Atlanta Arcade, Marol Church Road

Andheri (East), Mumbai- 400 059, India

12. WHO Reference Number (Prequalification Programme)

TB383

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. General classification for supply

Medicinal product subject to medical prescription

15. Instructions on use

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Strip pack carton

1. Name of the medicinal product

[TB383 trade name]

Pyridoxine hydrochloride 50 mg tablets

2. Statement of active substance

Each tablet contains 50 mg of pyridoxine hydrochloride.

3. List of excipients

4. Pharmaceutical form and contents

Tablets

9 x 10 tablets

10 x 10 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

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

Store in a dry place below 30°C, protected 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

Macleods Pharmaceuticals Ltd

304, Atlanta Arcade, Marol Church Road

Andheri (East), Mumbai- 400 059, India

12. WHO Reference Number (Prequalification Programme)

TB383

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. General classification for supply

Medicinal product subject to medical prescription

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Alu/Alu strips

1. Name of the medicinal product

[TB383 trade name]

Pyridoxine hydrochloride 50 mg tablets

2. Name of the supplier

Macleods Pharmaceuticals Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other