LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[TB401 trade name][*] Pyridoxine hydrochloride BP 50mg film-coated tablets

Pyridoxine hydrochloride

2. Statement of active substance

Each film-coated tablet contains 50 mg pyridoxine hydrochloride

3. List of excipients

Colour Titanium dioxide

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

10 x 10 tablets

10 x 50 tablets

10 x 100 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. Store tablets in blisters in the provided carton to protect from light.

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

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

11. Name and address of the supplier

S Kant Healthcare Ltd.
3-A, Shiv Sagar Estate, North Wing,
Dr. Annie Besant Road,
Worli, Mumbai – 400018,
India.

12. WHO Reference Number (Prequalification Programme)

TB401

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
Clear PVC/PVDC-Alu blisters

1. Name of the medicinal product
[TB401 trade name][†] Pyridoxine hydrochloride 50mg film-coated tablets

Pyridoxine hydrochloride

2. Name of the supplier
S Kant Healthcare Ltd.

3. Expiry date
EXP {MM/YYYY}

4. Manufacturer's batch number
<Batch> <Lot>{number}

5. Other

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