LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle Label

1. Name of the medicinal product

[TB193 trade name][1]Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin275 mg/75 mg/ 400 mg/150 mg tablets

Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin

2. Statement of active substance

Each tablet contains 275 mg ethambutol hydrochloride, 75 mg isoniazid, 400 mg pyrazinamide and 150 mg rifampicin.

3. List of excipients

See patient information leaflet for further information

4. Pharmaceutical form and contents

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 out of the reach and sight of children

Keep 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 in a dry place.

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

Svizera Europe BV

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

Antennestraat 84
P.O. Box 60300
1320 AS Almere
The Netherlands
Tel: +31 (0) 36 5397 340
Fax:+31 (0) 36 5397 349
E-mail: info@svizera.org

12. WHO Reference Number (Prequalification Programme)

TB193

13. Manufacturer's batch number

<Batch> {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

Carton label for blister pack

1. Name of the medicinal product

[TB193 trade name][2] Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin 275 mg/75 mg/ 400 mg/150 mg tablets

Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin

2. Statement of active substance

Each tablet contains 275 mg ethambutol hydrochloride, 75 mg isoniazid, 400 mg pyrazinamide and 150 mg rifampicin.

3. List of excipients

See patient information leaflet for further information

4. Pharmaceutical form and contents

24 x 28 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 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 in a dry place

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

Svizera Europe BV

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

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12. WHO Reference Number (Prequalification Programme)

TB193

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 STRIPS

1. Name of the medicinal product

[TB193 trade name][3] Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin 275 mg/75 mg/ 400 mg/150 mg tablets

Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin

2. Name of the supplier

SvizeraEurope BV

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}

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