

LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND THE IMMEDIATE PACKAGING

HDPE bottle/ carton

1. Name of the medicinal product

[TB192 trade name]* Ethambutol hydrochloride /isoniazid/ rifampicin 275mg/75mg/150mg tablets

Ethambutol hydrochloride /isoniazid/ rifampicin

2. Statement of active substance

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

3. List of excipients

4. Pharmaceutical form and contents

1000 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 out of the reach and sight of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 25° C. Protect from moisture. Protect from light.

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

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
Antennestraat 84
P.O. Box 60300
1322 AS Almere
The Netherlands

12. WHO Reference Number (Prequalification Programme)

TB192

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 AND THE IMMEDIATE PACKAGING

Blister carton

1. Name of the medicinal product

[TB192 trade name] Ethambutol hydrochloride /isoniazid/ rifampicin 275mg/75mg/150mg tablets

Ethambutol hydrochloride /isoniazid/ rifampicin

2. Statement of active substance

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

3. List of excipients

4. Pharmaceutical form and contents

24 x 28 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 out of the reach and sight of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 25° C. Protect from moisture. 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

Svizera Europe BV
Antennestraat 84
P.O. Box 60300
1322 AS Almere
The Netherlands

12. WHO Reference Number (Prequalification Programme)

TB192

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

1. Name of the medicinal product

[TB192 trade name] Ethambutol hydrochloride /isoniazid/ rifampicin 275mg/75mg/150mg tablets

Ethambutol hydrochloride /isoniazid/ rifampicin

2. Name of the supplier

Svizera Europe BV

3. Expiry date

EXP {MM/YYYY}

4. Special storage conditions

<Batch><Lot><BN> {number}