

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Bottle

1. Name of the medicinal product

[TB189 trade name]*isoniazid/rifampicin 75mg/150mg film-coated tablets

Isoniazid /rifampicin

2. Statement of active substance

Each tablet contains 75 mg isoniazid and 150 mg rifampicin.

3. List of excipients

Contains Lake of Ponceau 4R. See patient information leaflet for further information.

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 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 25°C and 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

Svizera Europe BV
Antennestraat 84
P.O. Box 60300
1322 AS Almere
The Netherlands
Tel: +3136 5397340
Fax: +31 36 5397349
e-mail: qm@svizera.com

12. WHO Reference Number (Prequalification Programme)

TB189

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

Blister

1. Name of the medicinal product

[TB189 trade name][†]isoniazid/rifampicin 75mg/150mg film-coated tablets

Isoniazid/rifampicin

2. Statement of active substance

Each tablet contains 75mg isoniazid and 150 mg rifampicin.

3. List of excipients

Contains Lake of Ponceau 4R. See patient information leaflet for further information.

4. Pharmaceutical form and contents

672 (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 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 25°C and 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.

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<Batch><Lot> {number}

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Medicinal product subject to medical prescription.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. Name of the medicinal product

[TB189 trade name] isoniazid/rifampicin 75mg/150mg film-coated tablets

Isoniazid/rifampicin

2. Name of the supplier

Svizera Europe BV

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch><Lot>{number}

5. Other