

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

Bottle label

1. NAME OF THE MEDICINAL PRODUCT

Ethionamide 250 mg Tablets*

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 250 mg ethionamide.

3. LIST OF EXCIPIENTS

See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

100 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 SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

* Trade names are not prequalified by WHO. This is under local drug regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

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

Micro Labs Limited
31, Race Course Road
Bangalore 560 001
Karnataka
INDIA

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

TB 242

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

Blister label

1. NAME OF THE MEDICINAL PRODUCT

Ethionamide 250 mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 250 mg ethionamide.

3. LIST OF EXCIPIENTS

This is not reflected on the outer cartons/ blister label as per last approved artwork,
See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

10 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 SIGHT AND REACH 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.

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

Micro Labs Limited
31, Race Course Road
Bangalore 560 001
Karnataka
INDIA

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

TB242

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

Ethionamide 250 mg Tablets

2. NAME OF THE SUPPLIER

Micro Labs Limited

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

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