WHOPAR part 5

Updated: August 2015

Ethionamide 250 mg Tablets, MacLeods, TB133

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE
THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING
Lahel

1. NAME OF THE MEDICINAL PRODUCT

Ethionamide 250 mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains 250 mg ethionamide

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

100 film coated tablets.

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use

Read the package 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 30°C in the original container, protected 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

Macleods Pharmaceuticals Ltd.
304, Atlanta Arcade,
Marol Church Road,
Andheri (East),
Mumbai- 400 059,
India
<{tel}>+91 22 6676 2800
<{fax}>+91 22 2821 6599
<{e-mail}>exports@macleodspharma.com

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

TB133

13. MANUFACTURER'S BATCH NUMBER

<BN> $\{$ number $\}$

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE
THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING
Carton

1. NAME OF THE MEDICINAL PRODUCT

Ethionamide 250 mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains 250 mg ethionamide

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

10 x 10 film coated tablets

10 x 9 film coated tablets

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use

Read the package 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

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EXP {MM/YYYY}

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<BN> {number}

14. 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

Macleods Pharmaceuticals Ltd.

3. EXPIRY DATE

 $EXP \left\{ MM/YYYY \right\}$

4. BATCH NUMBER

BN {number}