WHOPAR Part 5

**LABELLING** 

# PARTICULARS TO APPEAR ON THE OUTER PACKAGING Outer carton label

# 1. NAME OF THE MEDICINAL PRODUCT

Zinc (as sulfate) Dispersible Tablets 20 mg<sup>1</sup>

# 2. STATEMENT OF ACTIVE SUBSTANCE

Each dispersible tablet contains 54.89 mg zinc sulfate monohydrate equivalent to 20 mg of zinc.

# 3. LIST OF EXCIPIENTS

Aspartame

#### 4. PHARMACEUTICAL FORM AND CONTENTS

 $10 \times 10$  tablets

1 x 7 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.

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<sup>&</sup>lt;sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

# 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 and moisture. Store tablets in blisters in the provided carton.

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 Limited 304, Atlanta Arcade Marol Church road Andheri (East) Mumbai – 400 059, INDIA

Tel: +91-22-6676 2800 +91-22-6113 2900

Fax: +91 -22-2821 6599

# 12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

DI005

#### 13. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <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

Zinc (as sulfate) Dispersible Tablets 20 mg

# 2. NAME OF THE SUPPLIER

Macleods Pharmaceuticals Ltd

# 3. EXPIRY DATE

EXP {MM/YYYY}

#### 4. BATCH NUMBER

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