

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton (Alu/PVC/PVdC)

1. Name of the medicinal product

[DI005 trade name]* Zinc (as sulfate) dispersible tablets 20 mg
Zinc (as sulfate)

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

Dispersible tablets
10 × 10 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 this medicine 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. 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

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

Carton (Alu/Alu)

1. Name of the medicinal product

[DI005 trade name][†] Zinc (as sulfate) dispersible tablets 20 mg
Zinc (as sulfate)

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

Dispersible tablets

1 x 7 tablets

10 x 10 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 this medicine 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. Protect from light and moisture. Store tablets in blisters in the provided carton.

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<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 OR STRIP

Blister

1. Name of the medicinal product

[DI005 trade name] Zinc (as sulfate) dispersible tablets 20 mg
Zinc (as sulfate)

2. Name of the supplier

Macleods Pharmaceuticals Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other