

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

Outer carton label

### **1. Name of the medicinal product**

[DI011 trade name] \* Zinc (as sulfate monohydrate) 20 mg dispersible tablets

Zinc (as sulfate monohydrate)

### **2. Statement of active substance**

Each dispersible tablet contains 54.9 mg zinc sulfate monohydrate equivalent to 20 mg of zinc.

### **3. List of excipients**

The tablets contain aspartame.

See patient information leaflet for further information.

### **4. Pharmaceutical form and contents**

Dispersible Tablets

1 x 10 Tablets

3 x 10 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 moisture.

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

**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**

Ipca Laboratories Limited  
48 Kandivli Industrial Estate  
Kandivli (West)  
Mumbai 400 067  
India.

**12. WHO Reference Number (Prequalification Programme)**

DI011

**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**

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP**

PVdC/PVC-Alu blister or Alu-Alu blister strip

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Zinc (as sulfate monohydrate)

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48 Kandivli Industrial Estate

Kandivli (West)

Mumbai 400 067

India

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**