## **LABELLING**

#### PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

#### 1. Name of the medicinal product

 $[\mathrm{DI}010~\mathrm{trade~name}]^*$  zinc (as sulfate monohydrate) 10 mg/5 mL oral solution Zinc sulfate monohydrate

#### 2. Statement of active substance

Each 5 mL oral solution contains 27.45 mg zinc sulfate monohydrate equivalent to 10 mg elemental zinc.

## 3. List of excipients

Contains aspartame, sodium benzoate and sorbitol

#### 4. Pharmaceutical form and contents

Oral solution

60 mL oral solution

#### 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

Store below 30°C. Protect from light.

# 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

PharmEvo Private Limited A-29, North Western Industrial Zone Port Qasim Karachi-75020 Pakistan

## 12. WHO Reference Number (Prequalification Programme)

DI010

## 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 IMMEDIATE PACKAGING

Bottle label

#### 1. Name of the medicinal product

 $[DI010~trade~name]^\dagger$  zinc (as sulfate monohydrate) 10 mg/5 mL oral solution Zinc sulfate monohydrate

#### 2. Statement of active substance

Each 5 mL oral solution contains 27.45 mg zinc sulfate monohydrate equivalent to 10 mg elemental zinc.

## 3. List of excipients

Contains aspartame, sodium benzoate and sorbitol.

#### 4. Pharmaceutical form and contents

Oral solution

60 mL oral solution

#### 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

Store below 30°C. Protect from light.

# 10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

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<sup>&</sup>lt;sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Page 4 of 5

## 11. Name and address of the supplier

PharmEvo Private Limited A-29, North Western Industrial Zone Port Qasim Karachi-75020 Pakistan

## 12. WHO Reference Number (Prequalification Programme)

DI010

## 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