

## **LABELLING**

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

Carton label

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

[RH056 trade name]\*

Misoprostol 200µg tablets

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

Each uncoated tablet contains 200µg misoprostol.

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

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

Uncoated tablets

10x10 tablets

10x1x3 tablets

10x1x4 tablets

15x1x4 tablets

6x10 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. Store tablets in blisters in the provided cartons.

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

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

**11. Name and address of the supplier**

ACME Formulation Pvt. Ltd.  
Ropar Road, Nalagarh, Dist. Solan  
Himachal Pardesh-174101  
India

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

RH056

**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**

Blister (Alu-Alu)

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

[RH056 trade name]

Misoprostol 200µg tablets

### **2. Name of the supplier**

ACME Formulation Pvt. Ltd.

### **3. Expiry date**

EXP {MM/YYYY}

### **4. Manufacturer's batch number**

<Batch> <Lot>{number}

### **5. Other**