

## **LABELLING**

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

Carton/box label

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

[RH089 trade name]\* Mifepristone 200 mg tablets + Misoprostol 200 µg tablets  
Mifepristone + Misoprostol

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

Each yellowish, round tablet contains mifepristone 200 mg. Each white, hexagonal tablet contains misoprostol 200 µg.

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

See patient information leaflet

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

1 tablet of mifepristone 200 mg and 4 tablets of misoprostol 200 µg.

### **5. Method and route of administration**

Mifepristone tablets: oral use

Misoprostol tablets: vaginal, buccal or sublingual use

### **6. Special warning that the medicinal product must be stored out of the reach and sight of children**

Keep out of the 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. Store in the original package.

### **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**

China Resources Zizhu Pharmaceutical Co. Ltd. No.  
27, Chaoyang North Road  
Chaoyang District, Beijing 100024  
P. R. China

**12. WHO Reference Number (Prequalification Programme) RH089**

**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 BLISTERS OR STRIP**

Blister strip

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

[RH089 trade name] Mifepristone 200 mg tablets + Misoprostol 200 µg tablets Mifepristone  
+ Misoprostol

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

China Resources Zizhu Pharmaceutical Co. Ltd.

### **3. Expiry date**

EXP {MM/YYYY}

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

<Batch> <Lot>{number}