# PARTICULARS TO APPEAR ON THE OUTER PACKAGING CARTON LABEL

### 1. Name of the medicinal product

[RH048 trade name]\* Misoprostol 200 µg tablets Misoprostol

#### 2. Statement of active substance

Each tablet contains 200 µg misoprostol

### 3. List of excipients

Each tablet contains hydrogenated castor oil. See patient information leaflet for further information.

#### 4. Pharmaceutical form and contents

1 x 3 tablets

1 x 4 tablets

#### 5. Method and route of administration

Oral, vaginal, sublingual or buccal 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 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 in the original package.

## 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.

### 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)

RH048

### 13. Manufacturer's batch number

<Batch> {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

## 1. Name of the medicinal product

[RH048 trade name]  $^{\dagger}$  Misoprostol 200  $\mu g$  tablets Misoprostol

## 2. Name of the supplier

China Resources Zizhu Pharmaceutical Co., Ltd

## 3. Expiry date

EXP {MM/YYYY}

## 4. Manufacturer's batch number

<Batch> {number}

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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.