

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 vaginal 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

11. Name and address of the supplier

China Resources Zizhu Pharmaceutical Co. Ltd.
No. 27, Chaoyang North Road

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

Mifepristone + Misoprostol
200 mg/200 µg tablets, (China Resources
Zizhu Pharmaceutical Co Ltd), RH089

WHOPAR Part 5

March 2023

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

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3. Expiry date

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<Batch> <Lot>{number}