

PARTICULARS TO APPEAR ON THE OUTER PACKAGING CARTON LABEL

1. Name of the medicinal product

[RH094 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 4 tablets

2 x 4 tablets

3 x 4 tablets

15 x 4 tablets

30 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

Mylan Laboratories Limited,
Plot No. 564/A/22, Road No. 92,
Jubilee Hills
Hyderabad - 500096,
Telangana, India

12. WHO Reference Number (Prequalification Programme)

RH094

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

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Misoprostol

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