PARTICULARS TO APPEAR ON THE OUTER PACKAGING
CARTON LABEL

1. Name of the medicinal product

[RH039 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
7 x 4 tablets
15 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 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

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

11. Name and address of the supplier

Cipla Limited
Cipla House,
Peninsula Business Park
Ganpatrao Kadam Marg, Lower Parel
Mumbai -400013,
India
Phone: 9122 24826000
Fax: 9122 24826120

12. WHO Reference Number (Prequalification Programme)

RH039

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

[RH039 trade name] † Misoprostol 200 µg tablets

Misoprostol

2. Name of the supplier

Cipla Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}

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