

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label

1. Name of the medicinal product

[RH056 trade name]*

Misoprostol 200µg tablets

2. Statement of active substance

Each uncoated tablet contains 200µg misoprostol.

3. List of excipients

4. Pharmaceutical form and contents

Uncoated tablets

10 x 10 tablets

5. Method and route of administration

Oral 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 this medicine 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

11. Name and address of the supplier

ACME Formulation Pvt. Ltd.
Ropar Road, Nalagarh, Dist. Solan
Himachal Pardesh-174101

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

India

12. WHO Reference Number (Prequalification Programme)

RH056

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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blister

1. Name of the medicinal product

[RH056 trade name]

Misoprostol 200µg tablets

2. Name of the supplier

ACME Formulation Pvt. Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other