

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[RH087 trade name]*

Estradiol valerate /Norethisterone enantate 5mg/50mg/mL Solution for Injection

2. Statement of active substance

Each mL contains 5 mg estradiol valerate and 50 mg norethisterone enantate

3. List of excipients

The solution contains benzyl benzoate and castor oil

4. Pharmaceutical form and contents

Oil Solution for injection

5. Method and route of administration

Intramuscular injection

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 reach of children.

7. Other special warning(s), if necessary

Not during pregnancy and breastfeeding

After opening the box, use the product immediately and discard the syringe.

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C. Keep the prefilled glass syringe in the carton to protect the product from light. Do not refrigerate or freeze.

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

Bayer S.A. Av.

Luxemburgo N34-359 y Av.

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

Portugal Quito
Pichincha 170505
Ecuador
Personal information service: 1 800 229377

12. WHO Reference Number (Prequalification Programme)

RH087

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 SMALL IMMEDIATE PACKAGING UNITS

Glass Syringe

1. Name of the medicinal product and route(s) of administration

[RH087 trade name]

Estradiol valerate /Norethisterone enantate 5mg/50mg/mL Solution for Injection

Intramuscular injection

2. Method of administration

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Contents by weight, by volume, or by unit

1 mL

6. Other