

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[RH054 trade name]*

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

2. Statement of active substance

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

3. List of excipients

The solution contains benzyl benzoate

4. Pharmaceutical form and contents

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

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C. Protect from light.

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 AG,
Müllerstraße 178
13353 Berlin
Germany

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

12. WHO Reference Number (Prequalification Programme)
RH054

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 ampoules

- 1. Name of the medicinal product and route(s) of administration**
[RH054 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**