

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Noristerat
Norethisterone enantate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 ml contains Norethisterone enantate 200 mg in oily solution of benzylbenzoate and castor oil.

3. LIST OF EXCIPIENTS

N/A

4. PHARMACEUTICAL FORM AND CONTENTS

1 amp. 1ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular injection i.m.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

N/A

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store below 25°C
Protect from light

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR
WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

N/A

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bayer plc,
400 South Oak Way
Reading, RG2 6AD

12. MARKETING AUTHORISATION NUMBER(S)

PL 00010/0548

13. BATCH NUMBER<, DONATION AND PRODUCT CODES>

LOT

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

For use as directed by a medical practitioner.

16. INFORMATION IN BRAILLE

N/A (HCP use)

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:

MINIMUM PARTICULARS TO APPEAR ON AMPOULES
--

Ampoule

1. NAME OF THE MEDICINAL PRODUCT

Noristerat
Norethisterone enantate 200 mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER
--

(Bayer cross)

3. EXPIRY DATE

EXP

4. BATCH NUMBER<, DONATION AND PRODUCT CODES>
--

LOT

5. OTHER

1 ml i.m.