

**Levonorgestrel/Ethinylestradiol 150/30 Microgram Coated Tablets
PL 20117/0044**

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Levonorgestrel/Ethinylestradiol 150/30 Microgram Coated Tablets PL 20117/0044

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted a Marketing Authorisation for the medicinal product Levonorgestrel/Ethinylestradiol 150/30 microgram Coated Tablets (PL 20117/0044) to Morningside Healthcare Limited on 19 November 2012. This medicine is available on prescription from your doctor.

Levonorgestrel/Ethinylestradiol 150/30 microgram Tablets are a combined oral contraceptive and belong to a group of medicinal products often referred to as “the pill”. The tablets may be taken to prevent pregnancy.

Levonorgestrel/Ethinylestradiol 150/30 microgram Coated Tablets contain two hormones, estrogen (ethinylestradiol) and progestogen (levonorgestrel), as the active ingredients. These hormones prevent pregnancy, just as natural hormones would prevent conception during a pre-existing pregnancy.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Levonorgestrel/Ethinylestradiol 150/30 microgram Coated Tablets outweigh the risks, and a Marketing Authorisation has been granted.

Levonorgestrel/Ethinylestradiol 150/30 Microgram Coated Tablets
PL 20117/0044

SCIENTIFIC DISCUSSION

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INTRODUCTION

On 19 November 2012, the MHRA granted a Marketing Authorisation for the medicinal product Levonorgestrel/Ethinylestradiol 150/30 microgram Coated Tablets (PL 20117/0044) to Morningside Healthcare Limited . The product is a prescription-only medicine (POM) used for oral contraception.

The application was submitted as an abridged application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Femicept 150/30 Coated Tablets (alternative product name: Levest 150/30 Coated Tablets; PL 32821/0002), which was granted a Marketing Authorisation to Famy Care Europe Limited on 04 December 2009, following completion of the Decentralised Procedure (UK/H/1865/001/DC).

Levonorgestrel/Ethinylestradiol 150/30 microgram Coated Tablets are an estrogen-progestogen combination that works primarily by inhibiting ovulation. The tablets act on the hypothalamo-pituitary–ovarian axis to suppress the mid-cycle surge of luteinising hormone (LH). The tablets also alter cervical mucus making it impermeable to sperm and renders endometrium unreceptive to implantation.

No new data were submitted nor were necessary to be submitted for this simple application, as the data are identical to those of the previously granted cross-reference product.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 20117/0044
PROPRIETARY NAME: Levonorgestrel/Ethinylestradiol 150/30 microgram Coated Tablets
ACTIVE(S): Levonorgestrel and Ethinylestradiol
COMPANY NAME: Morningside Healthcare Limited
E.C. ARTICLE: Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS: POM

1. INTRODUCTION

This is an abridged application for Levonorgestrel/Ethinylestradiol 150/30 microgram Coated Tablets (PL 20117/0044), submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Femicept 150/30 Coated Tablets (PL 32821/0002), which was granted a Marketing Authorisation to Famy Care Europe Limited on 04 December 2009. The application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Levonorgestrel/Ethinylestradiol 150/30 microgram Coated Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Each coated tablet for oral use contains 150 micrograms levonorgestrel and 30 micrograms ethinylestradiol. The product is packaged in polvinylchloride/polvinylidene chloride/aluminium (PVC/PVDC/Al) blisters, in pack sizes of 21, 63, 126 and 273 coated tablets (1, 3, 6 and 13 blisters of 21 coated tablets, respectively). The blisters are packed with the Patient Information Leaflet into cardboard outer cartons.

The packaging, proposed shelf-life (3 years) and storage conditions ('Store below 25°C.') are consistent with the details registered for the cross-reference product.

2.3 Legal status

On approval, the product will be available as a prescription-only medicine (POM).

2.4 Marketing Authorisation Holder/Contact Persons/Company

Morningside Healthcare Ltd, 115 Narborough Road, Leicester, LE3 0PA, UK.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch sizes are stated.

2.8 Finished product/shelf-life specification

The proposed finished product specifications are in line with the details registered for the cross-reference product.

2.9 Drug substance specification

The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance

With the exception of lactose monohydrate, none of the excipients contain materials of animal or human origin.

The supplier of lactose monohydrate has confirmed that the milk used in the production of lactose monohydrate is sourced from healthy animals under the same conditions as those intended for human consumption. In addition, the supplier has confirmed that no ruminant material other than calf rennet is used during the production of lactose monohydrate.

2.11 Bioequivalence

No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula and utilise the same process as the reference product Femicept 150/30 Coated Tablets (PL 32821/0002).

3. EXPERT REPORT

The applicant cross-refers to the data for Femicept 150/30 Coated Tablets (PL 32821/0002), to which this application is claimed to be identical. This is acceptable.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product is identical to that for the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The proposed Summary of Product Characteristics is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING PIL

The Patient Information Leaflet has been prepared in-line with the details registered for the cross-reference product.

Famy Care Europe Limited (the marketing authorisation holder of the reference product for this application) submitted satisfactory PIL user testing for the PIL for Femicept 150/30 Coated tablets (PL 32821/0002) previously, in accordance with Article 59 of Council Directive 2001/83/EC.

User testing of the package leaflet for Levonorgestrel/Ethinylestradiol 150/30 microgram Coated Tablets (PL 20117/0044) has been accepted based on bridging report provided by the applicant making reference to the user-testing of the PIL for Femicept 150/30 Coated Tablets (PL 32821/0002), as the 'parent PIL'. As the proposed and reference leaflets are considered the same, no further user testing of the leaflet for this product is necessary.

Carton and label-leaflet

The proposed artwork is consistent with the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation, the applicant has also included the name of the product in Braille on the outer packaging.

7. CONCLUSION

The data submitted with this application is acceptable. The grant of a Marketing Authorisation is recommended.

NON-CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided an Environmental Risk Assessment in accordance with EMEA/CHMP/SWP/4447/00. As the application is for an identical version of an already authorised product, it is not expected that environmental exposure will increase following approval of the Marketing Authorisation for the proposed product.

The grant of a Marketing Authorisation is recommended.

CLINICAL ASSESSMENT

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

The Marketing Authorisation Holder has not submitted a Risk Management Plan (RMP). As the application is for an identical version of an already authorised reference product, for which safety concerns requiring additional risk minimisation have not been identified, a Risk Management Plan is not considered necessary. The reference product has been in use for many years and the safety profiles of the active ingredients are well-established.

The grant of a Marketing Authorisation is recommended.

OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY

The data for this application is consistent with that previously assessed for the cross-reference product and as such have been judged to be satisfactory.

NON-CLINICAL

No new non-clinical data were submitted and none are required for this application.

EFFICACY

This application is identical to the previously granted application Femicept 150/30 Coated Tablets (PL 32821/0002).

SAFETY

No new safety data were supplied or required for this application. Levonorgestrel and ethinylestradiol have well-established safety profiles. No new or unexpected safety concerns arose from this application.

PRODUCT LITERATURE

The SmPC, PIL and labelling are acceptable. The SmPC is consistent with that for Femicept 150/30 Coated Tablets (PL 32821/0002). The PIL is consistent with the details in the SmPC and in-line with the current guidelines. The labelling is in-line with current guidance.

BENEFIT/RISK ASSESSMENT

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with levonorgestrel and ethinylestradiol in combination is considered to have demonstrated the therapeutic value of the product. The benefit/risk balance is, therefore, considered to be positive.

Levonorgestrel/Ethinylestradiol 150/30 Microgram Coated Tablets PL 20117/0044

STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the Marketing Authorisation application on 14 May 2012.
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 21 June 2012.
- 3 Following assessment of the application, the MHRA requested further information relating to the dossier on 17 July 2012 and 13 September 2012.
- 4 The applicant responded to the MHRA's requests, providing further information on the dossier on 05 September 2012 and 10 October 2012.
- 5 The application was granted on 19 November 2012.

SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

PATIENT INFORMATION LEAFLET

In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

LABELLING

The Marketing Authorisation Holder has submitted the below text version of the labelling and has committed to submitting the mock-ups to the competent authorities before marketing any pack size.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON BOX

1. NAME OF THE MEDICINAL PRODUCT

Levonorgestrel/Ethinylestradiol 150/30 micrograms Coated Tablets
Levonorgestrel/Ethinylestradiol

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each coated tablet contains:
150 mcg of Levonorgestrel
30 mcg of Ethinylestradiol

3. LIST OF EXCIPIENTS

Each coated tablet contains 58.17mg Lactose Monohydrate and 12.03 mg of sucrose.

4. PHARMACEUTICAL FORM AND CONTENTS

Coated Tablet

21 tablets
63 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.
For use as directed by a medical practitioner

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
exp
Exp

9. SPECIAL STORAGE CONDITIONS

Store below 25°C.

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 MARKETING AUTHORISATION HOLDER

Morningside Healthcare Ltd
115 Narborough Road.
Leicester
LE3 0PA
UK

12. MARKETING AUTHORISATION NUMBER(S)

PL 20117/0044

13. BATCH NUMBER

Lot
lot
BN
bn

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Levonorgestrel/Ethinylestradiol 150/30mcg Coated Tablets

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
--

OPA/Aluminium/PVC/Aluminium blister strips
--

1. NAME OF THE MEDICINAL PRODUCT

Levonorgestrel/Ethinylestradiol 150/30 micrograms Coated Tablets,
Levonorgestrel/Ethinylestradiol

2. NAME OF THE MARKETING AUTHORISATION HOLDER
--

Morningside Healthcare Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot:

5. OTHER

Weekdays to be indicated on blister strips.