CIMIZT 150 MICROGRAM/30 MICROGRAM TABLETS

PL 20117/0231

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PL 20117/0231

LAY SUMMARY

The Medicine and Healthcare Regulatory Agency (MHRA) granted Morningside Healthcare Limited a Marketing Authorisation (licence) for the medicinal product Cimizt 150 microgram/30 microgram Tablets on 28 May 2012. This is a prescription only medicine (POM).

Cimizt 150 microgram/30 microgram Tablets is a combined oral contraceptive and belongs to a group of medicinal product often referred to as 'the pill'. This medicine may be taken to prevent pregnancy.

Cimizt 150 microgram/30 microgram Tablets contain a small amount of two types of female hormones, progestogen (desogestrel) and estrogen,(ethinylestradiol) as the active ingredients. These hormones prevent pregnancy, just as natural hormones would prevent conception during a pre-existing pregnancy.

The combined contraceptive pill protects against getting pregnant in three ways. These hormones:

1. Stop the ovary from releasing an egg each month (ovulation).
2. Also thicken the fluid (at the neck of the womb making it more difficult for the sperm to reach the egg.
3. Alter the lining of the womb to make it less likely to accept a fertilised egg.

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

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted a Marketing Authorisation for the medicinal product Cimizt 150 microgram/30 microgram Tablets (PL 20117/0231) to Morningside Healthcare Limited on 28 My 2012. This is a prescription only medicine (POM) used for oral contraception.

Cimizt 150 microgram/30 microgram Tablets are a progestogen and estrogen, fixed combination oral contraceptive with ethinylestradiol and the progestogen desogestrel. Ethinylestradiol is a well known synthetic estrogen and desogestrel is a synthetic progestogen. The tablets act by preventing ovulation. Direct measurements of plasma hormone levels indicate that luteinising hormone (LH) and Follicle-stimulating hormone (FSH) levels are suppressed, a mid-cycle surge of LH is absent, endogenous steroid levels are diminished and ovulation does not occur. While either component alone can be shown to exert these effects in certain situations, the combination synergistically decreases plasma gonadotropin levels and suppresses ovulation more consistently than either alone.

The application was submitted as a simple abridged application, according to Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC, cross-referring to Desogestrel/Ethinylestradiol 150/30 microgram tablets (PL 32821/0049), which was granted a Marketing Authorisation to Famy Care Europe Limited on 15 December 2001.

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

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 20117/0231
PROPRIETARY NAME: Cimizt 150 microgram/30 microgram Tablets
ACTIVE(S): Ethinylestradiol and Desogestrel
COMPANY NAME: Morningside Healthcare Limited
E.C. ARTICLE: Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC
LEGAL STATUS: POM

1. INTRODUCTION

This is an abridged simple, informed consent application for Cimizt 150 microgram/30 microgram Tablets submitted under Article 10c of Directive 2001/83/EC. The proposed Marketing Authorisation Holder is Morningside Healthcare Limited, 115, Narborough Road, Leicester, LE3 0PA, UK, United Kingdom.

The application cross-refers to Desogestrel/Ethinylestradiol 150/30 microgram tablets (PL 32821/0049), which was granted a Marketing Authorisation to Famy Care Europe Limited on 15 December 2011.

The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

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

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

Each tablet contains 150 micrograms desogestrel and 30 micrograms ethinylestradiol.as the active ingredients.

The tablets are packaged in:

1) Clear transparent poly vinylchloride (PVC)/ polyvinylidenechloride (PVdC) - Aluminium blister of 21 tablets per calendar blister strip available in packs containing 1x21, 3x21 or 6x21 tablets. Each blister is packed in tri-laminated pouch or
2) Clear transparent PVC/PVdC- Aluminium blister of 21 tablets per calendar blister strip available in packs containing 1x21, 3x21 or 6x21 tablets. Each blister is packed in tri-laminated pouch along with 2g molecular sieve.

It has been stated that not all pack sizes may be marketed, however, the Marketing Authorisation Holder has committed to submitting the mock-ups for any pack size to the competent authority for approval before marketing.

The proposed shelf-life (2 years) and storage conditions ('Do not store above 25°C and store in the original package in order to protect from moisture and light.') 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 (POM) medicine.

2.4 Marketing Authorisation Holder/Contact Persons/Company
Morningside Healthcare Limited, 115, Narborough Road, Leicester, LE3 0PA, UK

The qualified person responsible for pharmacovigilance is stated and their CV is included.

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 size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is 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.

European Directorate for the Quality of Medicines (EDQM) Certificates of Suitability for the drug substance manufacturers has been provided to support the manufacturing and control of active substances. These details are in line with those of the reference product.

2.10 TSE Compliance
With the exception of lactose anhydrous, no materials of animal or human origin are included in the product. This is consistent with the cross reference product.

The applicant has provided TSE Certificates of Suitability to show that lactose anhydrous is provided by appropriate sources.

2.11 Bioequivalence
No bioequivalence data are required to support this simple abridged application, as the proposed product is manufactured to the same formula utilising the same process as the cross-reference product Desogestrel/Ethinylestradiol 150/30 microgram tablets (PL 32821/0049).

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3. EXPERT REPORTS

The applicant cross-refers to the data for Desogestrel/Ethinylestradiol 150/30 microgram tablets (PL 32821/0049), to which it claims identicality. 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 the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

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

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING

The patient information leaflet and labelling have been prepared in line with the details registered for the cross-reference product

Famy Care Europe Limited has previously submitted results of PIL user testing, in accordance with Article 59 of Council Directive 2001/83/EC for the reference product Desogestrel/Ethinylestradiol 150/30 microgram tablets (PL 32821/0049). The results indicate that the leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.
As the leaflet for the reference product and this product is considered the same, no further user testing of the leaflet for this product is necessary. The Marketing Authorisation Holder has provided a report to bridge the leaflet for Cimizt 150 microgram/30 microgram Tablets; PL 20117/0231 (daughter) to the parent leaflet for the reference product (Desogestrel/Ethinylestradiol 150/30 microgram tablets, PL 32821/0049). This is acceptable.

The proposed artwork is comparable to 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. CONCLUSIONS

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

PRECLINICAL ASSESSMENT

No new preclinical data have been submitted with this application and none are required for an application of this type.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA). As the application is for an identical version of an already authorised reference product, it is not expected that the environmental exposure to ethinylestradiol and desogestrel will increase following the marketing approval of the product.

The grant of a Marketing Authorisation is recommended.

CLINICAL ASSESSMENT

No new clinical data have been submitted with this application and none are required for an application of this type.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that the Marketing Authorisation Holder has the services of a qualified person responsible for pharmacovigilance and has 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 provided an adequate justification for not submitting 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 minimisation system is not considered necessary. The reference product has been in use for many years and the safety profile of the active ingredient is 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.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

This application is identical to a previously granted application for Desogestrel/Ethinylestradiol 150/30 microgram tablets (PL 32821/0049).

No new or unexpected safety concerns arise from this application.

The SmPC, leaflet and labelling are satisfactory and consistent with that for the cross-reference product.

BENEFIT/RISK ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with ethinylestradiol and desogestrel is considered to have demonstrated the therapeutic value of the compound. The benefit/risk is, therefore, considered to be positive.

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STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 17 January 2012.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 30 March 2012.
3	Following assessment of the application the MHRA requested further information on 02 April 2012 and 09 May 2012.
4	The applicant responded to the MHRA's request, providing further information on 05 April 2012 and 10 May 2012.
5	The application was determined on 28 May 2012.

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

CIMIZT 150 MICROGRAM/30 MICROGRAM TABLETS
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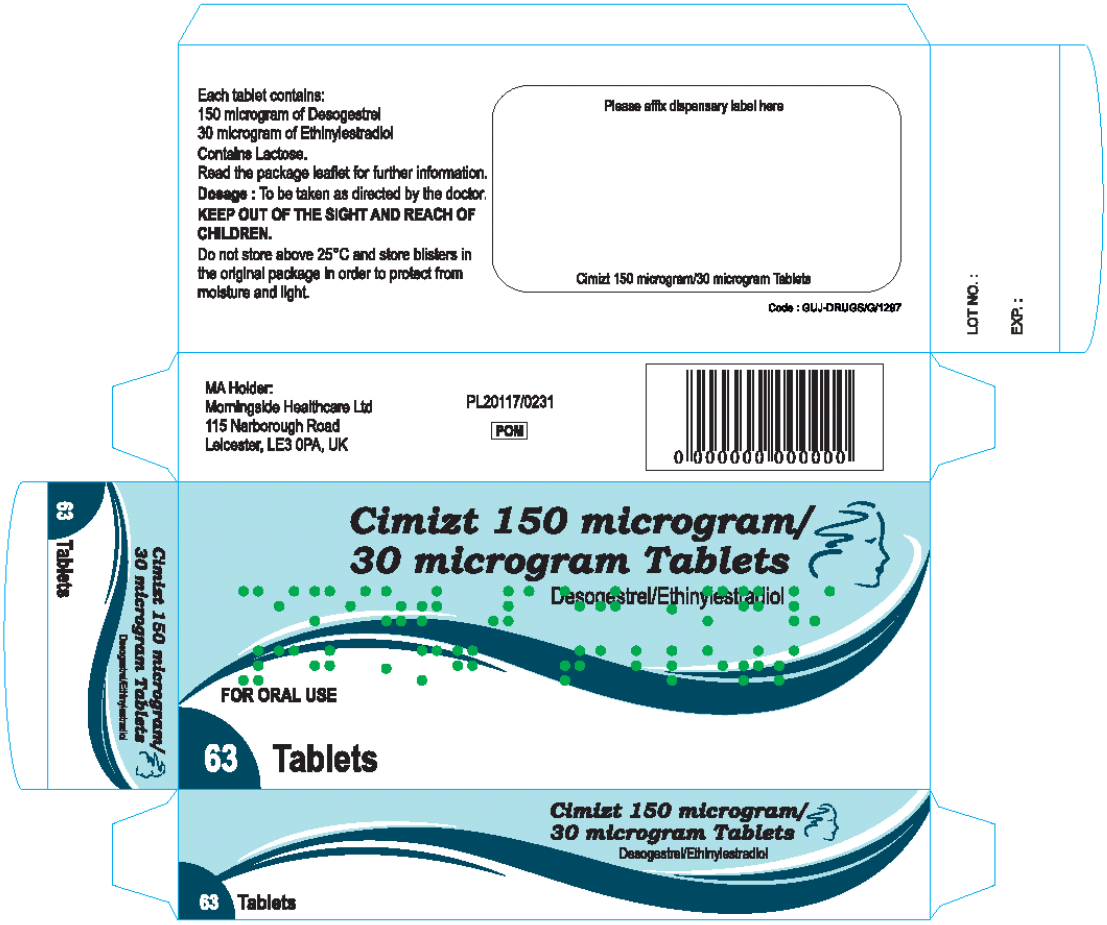
SUMMARY OF PRODUCT CHARACTERISTICS

The Summary of Product Characteristics for this product is published on the MHRA website.

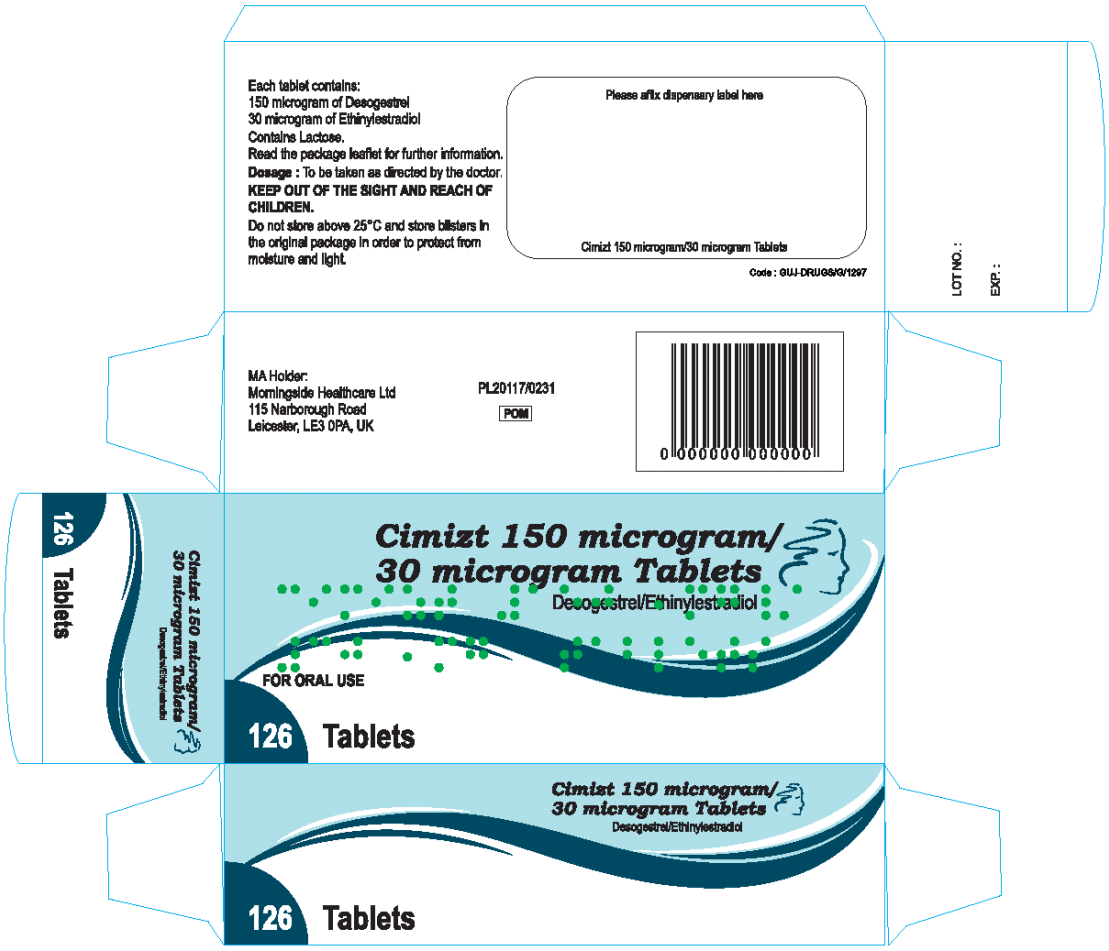
PRODUCT INFORMATION LABEL/LEAFLET

Carton

Cimizt #150 µg/
#30 µg Tablets



Cimizt #150 µg/
#30 µg Tablets



Cimizt #150 µg/
#30 µg Tablets

Blister

PRODUCT INFORMATION LEAFLET

The Patient Information Leaflet for this product is published on the MHRA website.