Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Danesh Gadhia
MORNINGSIDE HEALTHCARE LIMITED
MORNINGSIDE HOUSE
UNIT C, HARCOURT WAY, MERIDIAN BUSINESS PARK
LEICESTER
LE19 1WP
UNITED KINGDOM

27/12/2019

Dear Mr Gadhia,

GRANT OF MARKETING AUTHORISATION

Our Reference:	PL 20117/0364 - 0001
Your Reference:	20117
Product:	Desogestrel 75 microgram Film-coated Tablets
Type of Procedure:	Mutual Recognition
Submission Type:	Change of Ownership
Submission Category:	Change of Ownership
EU Procedure Number (if applicable):	DE/H/5796/001/MR

The Licensing Authority agrees to the grant of the marketing authorisation for the above submission on the basis of the data provided. This includes any replacement and amendment of the original dossier.

In line with Article 23a of Directive 2001/83/EC as amended, the Marketing Authorisation Holder should submit notification of the actual date of marketing of the product to the Competent Authority.
This notification should be provided by email to the following address: sunsetclause@mhra.gov.uk.

The formal documents are enclosed. These constitute evidence of authorisation. If you consider them to contain information that is incorrect or not in accordance with the dossier, please return immediately indicating any errors.

All Marketing Authorisations are subject to standard provisions contained in current medicines regulations full details of which are published on the MHRA **website.**

Yours sincerely,

MHRA

Digitally signed by Moraru Grigore
Date: 2023.10.20 19:18:02 EEST
Reason: MoldSign Signature
Location: Moldova

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The Medicines for Human Use (Marketing Authorisations etc.) Regulations, SI 1994/3144, as amended.

GRANT OF MARKETING AUTHORISATION

Product: Desogestrel 75 microgram Film-coated Tablets
Submission Type: Change of Ownership

Granted to: MORNINGSIDE HEALTHCARE LIMITED
MORNINGSIDE HOUSE
UNIT C, HARCOURT WAY, MERIDIAN BUSINESS PARK
LEICESTER
LE19 1WP
UNITED KINGDOM

This Marketing Authorisation, under the above reference number is hereby granted in respect of the product named above.

The application is subject to the further provisions set out or referred to in the above Regulations.

This Marketing Authorisation, as now granted, unless previously revoked, will continue in force until the expiry date (if applicable) given below.

Grant Date: 27/12/2019

Date of Expiry:

As this grant relates to a Change of Ownership application, you are reminded that you must:

1. Immediately notify the Licensing Authority if the pharmacovigilance system utilised for this product and/or the EEA Qualified Person Responsible for Pharmacovigilance (QPPV), as recorded in the original authorisation, has changed, in accordance with the variations regulation:

http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/betterreg/pharmacos/classification_guideline_adopted.pdf

and

2. Carry out any obligation to supply on-going information about the product and any obligation specified within the Risk Management Plan (if applicable), or any other risk minimisation activities which the current marketing authorisation holder has previously given to the Licensing Authority.

Please note that, under the “Sunset Clause” provisions, the marketing authorisation (MA) holder is required to notify the competent authority (MHRA in the UK) of the date of actual marketing of the medicinal product, taking account of the various presentations authorised, and to notify the competent authority if the product ceases to be placed on the market either temporarily or permanently. The MA for any product that is not placed on the market for a period of three consecutive years will cease to be valid. It is important to note that if a product undergoing a Change of Ownership is currently not marketed, the new MA will inherit the marketed status and last marketed date of the old MA for the purposes of the Sunset Clause. For more information see www.mhra.gov.uk/SunsetClause.

MHRA
A person authorised to sign on behalf of the Secretary of State for Health