

Head Of Regulatory Affairs  
MORNINGSIDE HEALTHCARE LIMITED  
115 NARBOROUGH ROAD  
LEICESTER  
LE3 OPA  
UNITED KINGDOM

31/07/2009

Dear Sir / Madam,

**GRANT / RENEWAL OF MARKETING AUTHORISATION**

Our Reference: PL 20117/0119 - 0001  
Your Reference: 20117  
Product: Buprenorphine 2mg Sublingual Tablets

Type of Procedure: Decentralised  
Submission Type: Initial  
Submission Category: Abridged  
EU Procedure Number (if applicable): UK/H/1827/02/DC

The Licensing Authority agrees to the grant or renewal 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.

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.

In addition the product shall not be marketed in the UK till Morningside Healthcare's Pharmacovigilance System has been re-inspected to confirm resolution of outstanding issues.

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

<http://www.mhra.gov.uk/mhra/marketingauthorisationprovisions>

Yours sincerely,

Renu Raizada

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

**GRANT / RENEWAL OF MARKETING AUTHORISATION**

Product: PL 20117/0119 Buprenorphine 2mg Sublingual Tablets  
Submission Type: Initial

Granted to: MORNINGSIDE HEALTHCARE LIMITED  
115 NARBOROUGH ROAD  
LEICESTER  
LE3 OPA  
UNITED KINGDOM

This Marketing Authorisation, under the above reference number is hereby granted / renewed in respect of the product named above. The Summary of Product Characteristics of the product is set out in the attached document.

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

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

Grant Date: 31/07/2009

Date of Expiry: 30/03/2012

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

Head Of Regulatory Affairs  
MORNINGSIDE HEALTHCARE LIMITED  
115 NARBOROUGH ROAD  
LEICESTER  
LE3 OPA  
UNITED KINGDOM

31/07/2009

Dear Sir / Madam,

**GRANT / RENEWAL OF MARKETING AUTHORISATION**

Our Reference: PL 20117/0120 - 0001  
Your Reference: 20117  
Product: Buprenorphine 8mg Sublingual Tablets

Type of Procedure: Decentralised  
Submission Type: Initial  
Submission Category: Abridged  
EU Procedure Number (if applicable): UK/H/1827/03/DC

The Licensing Authority agrees to the grant or renewal 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.

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.

In addition the product shall not be marketed in the UK till Morningside Healthcare's Pharmacovigilance System has been re-inspected to confirm resolution of outstanding issues.

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Yours sincerely,

Renu Raizada

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

**GRANT / RENEWAL OF MARKETING AUTHORISATION**

Product: PL 20117/0120 Buprenorphine 8mg Sublingual Tablets  
Submission Type: Initial

Granted to: MORNINGSIDE HEALTHCARE LIMITED  
115 NARBOROUGH ROAD  
LEICESTER  
LE3 OPA  
UNITED KINGDOM

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