CLOBETASOL PROPIONATE/NEOMYCIN SULPHATE/NYSTATIN 0.5 MG/5 MG/100,000 IU/G CREAM
PL 17736/0128

CLOBETASOL PROPIONATE/NEOMYCIN SULPHATE/NYSTATIN 0.5 MG/5 MG/100,000 IU/G OINTMENT
PL 17736/0129

UKPAR

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LAY SUMMARY

On 12 November 2012, the MHRA granted Chemidex Pharma Limited Marketing Authorisations (licences) for the medicinal products Clobetasol propionate/neomycin sulphate/nystatin 0.5 mg/5 mg/100,000 IU/g Cream/Ointment (PL 17736/0128-9).

These are prescription-only medicines (legal status POM) containing the active ingredients clobetasol propionate, neomycin sulphate and nystatin. They are used to help reduce the redness and itchiness of certain skin problems. These skin problems include eczema or psoriasis,where an infection may be a problem.

Clobetasol propionate belongs to a group of medicines called steroids. It helps to reduce swelling and irritation of the skin. Neomycin sulphate and nystatin are anti-infective medicines. They fight bacterial and fungal infections of the skin.

No new or unexpected safety concerns arose from these applications and it was, therefore, judged that the benefits of taking Clobetasol propionate/neomycin sulphate/nystatin 0.5 mg/5 mg/100,000 IU/g Cream/Ointment outweigh the risks, hence Marketing Authorisations have been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted Marketing Authorisations for the medicinal products Clobetasol propionate/neomycin sulphate/nystatin 0.5 mg/5 mg/100,000 IU/g Cream/Ointment (PL 17736/0128-9) on 12 November 2012 to Chemidex Pharma Limited.

These are applications for Clobetasol propionate/neomycin sulphate/nystatin 0.5 mg/5 mg/100,000 IU/g Cream/Ointment (PL 17736/0128-9), submitted as abridged simple applications according to Article 10c of Directive 2001/83/EC, cross-referring to Clobetasol propionate/neomycin sulphate/nystatin 0.5mg/5mg/100,000 IU/g Cream/Ointment (Dermovate NN Cream/Ointment), which were originally granted licences to Glaxo Operations UK Limited in May 1993. Changes of ownership applications were granted to transfer these to Chemidex Pharma Limited on 30 May 2008 (PL 17736/0100-1).

These are prescription-only medicines (legal status POM) that are of particular value when used in short courses for the treatment of recalcitrant eczemas, neurodermatoses, and other conditions that do not respond satisfactorily to less active steroids. They are also indicated in more resistant dermatoses, such as recalcitrant eczemas and psoriasis (excluding widespread plaque psoriasis), where secondary bacterial or candidal infection is present, suspected or likely to occur, as when using occlusive dressings.

Clobetasol propionate is a very active topical corticosteroid. Neomycin sulphate is an aminoglycoside antibiotic. Nystatin is a polyene antifungal medication.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 17736/0128-9
PROPRIETARY NAME(S): Clobetasol propionate/neomycin sulphate/nystatin 0.5 mg/5 mg/100,000 IU/g Cream/Ointment
ACTIVE(S): Clobetasol propionate/neomycin sulphate/nystatin
COMPANY NAME: Chemidex Pharma Limited
E.C. ARTICLE: Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC
LEGAL STATUS: POM

1. INTRODUCTION

These are simple, piggyback applications for Clobetasol propionate/neomycin sulphate/nystatin 0.5 mg/5 mg/100,000 IU/g Cream/Ointment submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Chemidex Pharma Limited, T/A Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB.

The applications cross-refer to Clobetasol propionate/neomycin sulphate/nystatin 0.5mg/5mg/100,000 IU/g Cream/Ointment (Dermovate NN Cream/Ointment), which were originally granted licences to Glaxo Operations UK Limited in May 1993. Changes of ownership applications were granted to transfer these to Chemidex Pharma Limited on 30 May 2008 (PL 17736/0100-1).

The current applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 NAME(S)

The proposed names of the products are Clobetasol propionate/neomycin sulphate/nystatin 0.5 mg/5 mg/100,000 IU/g Cream and Clobetasol propionate/neomycin sulphate/nystatin 0.5 mg/5 mg/100,000 IU/g Ointment. The products have been named in-line with current requirements.

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

The products contain clobetasol propionate 0.05% w/w, neomycin sulphate 0.5% w/w and nystatin 100,000 IU per gram. They are to be packed in collapsible aluminium tubes with polypropylene caps in pack sizes of 25 and 30g..

The proposed shelf-lives (18 months and 36 months for the cream and ointment, respectively) 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 products will be available as prescription-only medicines (legal status POM).

2.4 Marketing authorisation holder/Contact Persons/Company

Chemidex Pharma Limited, T/A Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB.

The QP responsible for pharmacovigilance is stated and his 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 compositions are consistent with the details registered for the cross-reference products.

2.7 Manufacturing process
The proposed manufacturing processes are consistent with the details registered for the cross-reference products 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 products.

2.9 Drug substance specification
The proposed drug substance specifications are consistent with the details registered for the cross-reference products.

2.10 TSE Compliance
With the exception of the active substance nystatin and the excipient white beeswax in the cream formulation, no materials of animal or human origin are included in these products. Nystatin and white beeswax are not sourced from animals that are considered a TSE risk. These details are consistent with the cross-reference products.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product names. The appearance of the products is identical to their respective cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The proposed SmPCs are consistent with the details registered for the respective cross-reference products.

6. PATIENT INFORMATION LEAFLET (PIL)/CARTON
PIL
The patient information leaflets have been prepared in-line with the details registered for the respective cross-reference products.

Carton and blister

The proposed artwork is comparable to the artwork registered for the cross-reference products 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 and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with these applications are acceptable. From a quality perspective, Marketing Authorisations should be granted.

NON-CLINICAL ASSESSMENT

No new non-clinical data have been supplied with these applications and none are required for applications of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with these applications and none are required for applications of this type.

OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY

Clobetasol propionate/neomycin sulphate/nystatin 0.5 mg/5 mg/100,000 IU/g Cream/Ointment are identical to the already licensed reference products. The products are, therefore, pharmaceutically satisfactory.

NON-CLINICAL

No new non-clinical data were submitted and none are required for applications of this type.

CLINICAL PHARMACOLOGY/EFFICACY

No new clinical pharmacology/efficacy data have been submitted with these applications and none are required for applications of this type.

SAFETY

No new safety data have been submitted with these applications and none are required for applications of this type.

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory.

BENEFIT-RISK ASSESSMENT

The quality of the products is acceptable and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with clobetasol propionate, neomycin sulphate and nystatin is considered to have demonstrated the therapeutic value of the compounds. The benefit-risk is, therefore, considered to be positive.

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CLOBETASOL PROPIONATE/NEOMYCIN SULPHATE/NYSTATIN 0.5 MG/5 MG/100,000 IU/G OINTMENT PL 17736/0129

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation applications on 21 May 2011
2	Following standard checks and communication with the applicant, the MHRA considered the applications valid on 10 June 2011
3	Following assessment of the applications, the MHRA requested further information relating to the dossiers on 15 November 2011
4	The applicant responded to the MHRA's requests, providing further information on 16 February 2012
5	The applications were determined on 12 November 2012

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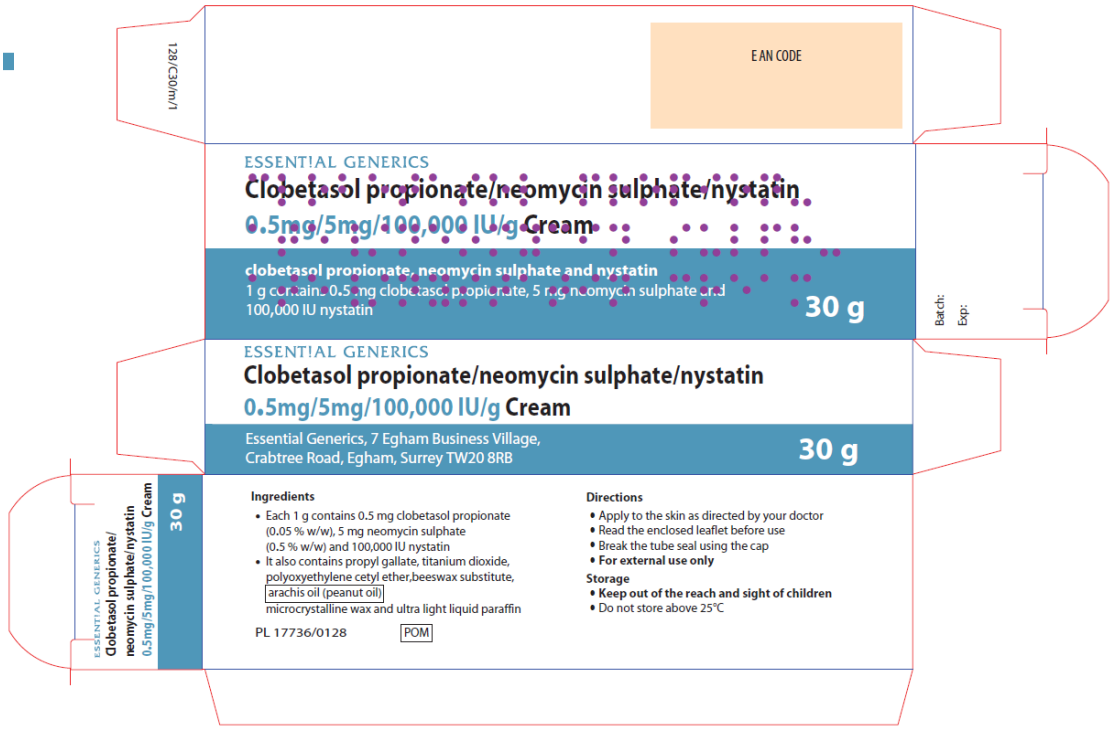
STEPS TAKEN AFTER AUTHORISATION - SUMMARY

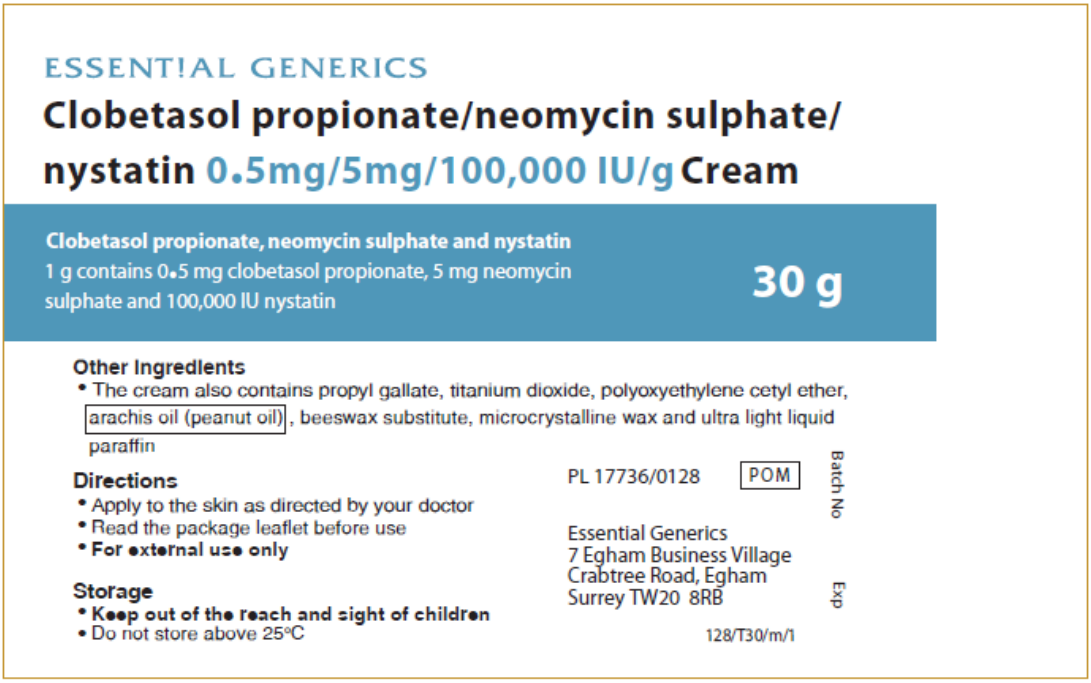
Date submitted	Application type	Scope	Outcome

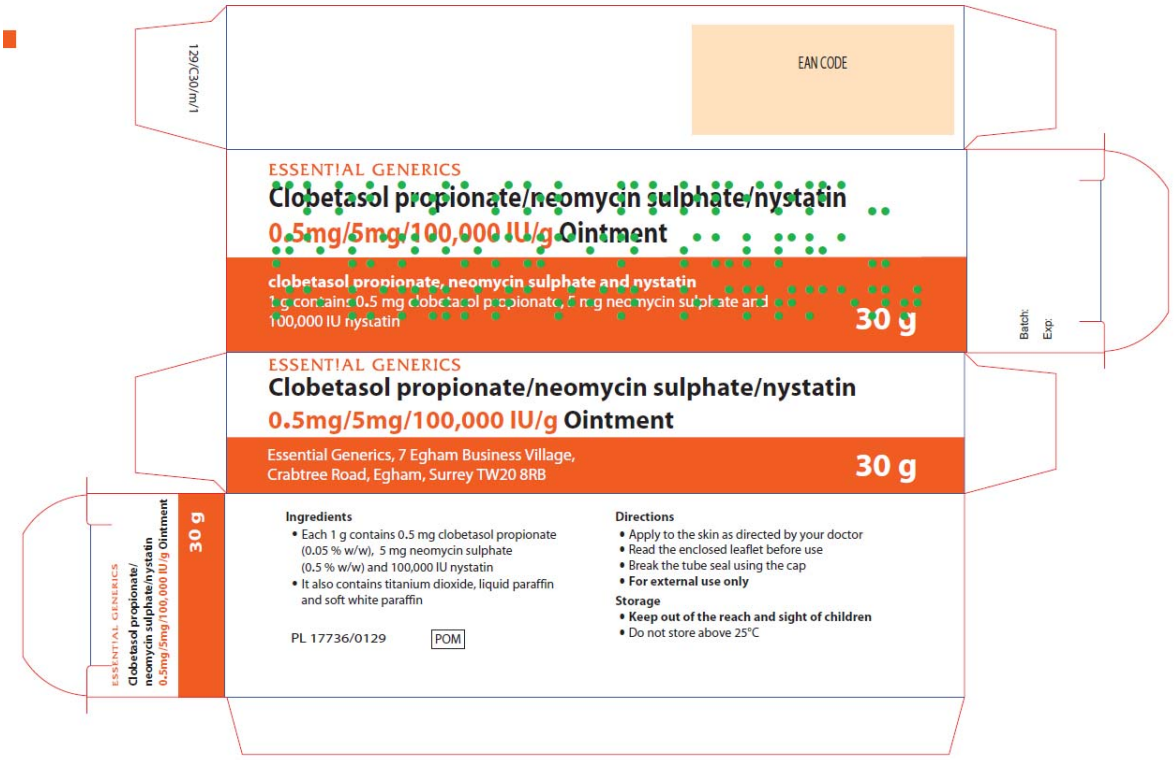
Summary of Product Characteristics and Patient Information Leaflet

The current approved UK versions of the Summary of Product Characteristics (SmPCs) and Patient Information Leaflet (PILs) for these products is available on the MHRA website.

Labelling


128/C30/m/1
EAN CODE
ESSENTIAL GENERICS
Clobetasol propionate/neomycin sulphate/nystatin
0.5mg/5mg/100,000 IU/g Cream
clobetasol propionate, neomycin sulphate and nystatin
1 g contains 0.5 mg clobetasol propionate, 5 mg neomycin sulphate and 100,000 IU nystatin
30 g
Batch:
Exp:
ESSENTIAL GENERICS
Clobetasol propionate/neomycin sulphate/nystatin
0.5mg/5mg/100,000 IU/g Cream
Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RB
30 g
ESSENTIAL GENERICS
Clobetasol propionate/ neomycin sulphate/nystatin 0.5mg/5mg/100,000 IU/g Cream
30 g
Ingredients
• Each 1 g contains 0.5 mg clobetasol propionate (0.05 % w/w), 5 mg neomycin sulphate (0.5 % w/w) and 100,000 IU nystatin
• It also contains propyl gallate, titanium dioxide, polyoxyethylene cetyl ether,beeswax substitute, arachis oil (peanut oil) microcrystalline wax and ultra light liquid paraffin
PL 17736/0128
POM
Directions
• Apply to the skin as directed by your doctor
• Read the enclosed leaflet before use
• Break the tube seal using the cap
• For external use only
Storage
• Keep out of the reach and sight of children
• Do not store above 25°C


ESSENTIAL GENERICS
Clobetasol propionate/neomycin sulphate/nystatin 0.5mg/5mg/100,000 IU/g Cream
Clobetasol propionate, neomycin sulphate and nystatin
1 g contains 0.5 mg clobetasol propionate, 5 mg neomycin sulphate and 100,000 IU nystatin
30 g
Other Ingredients
• The cream also contains propyl gallate, titanium dioxide, polyoxyethylene cetyl ether, arachis oil (peanut oil), beeswax substitute, microcrystalline wax and ultra light liquid paraffin
Directions
• Apply to the skin as directed by your doctor
• Read the package leaflet before use
• For external use only
Storage
• Keep out of the reach and sight of children
• Do not store above 25°C
PL 17736/0128
POM
Batch No
Essential Generics
7 Egham Business Village
Crabtree Road, Egham
Surrey TW20 8RB
Exp
128/T30/m/1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EAN CODE
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0.5mg/5mg/100,000 IU/g Ointment
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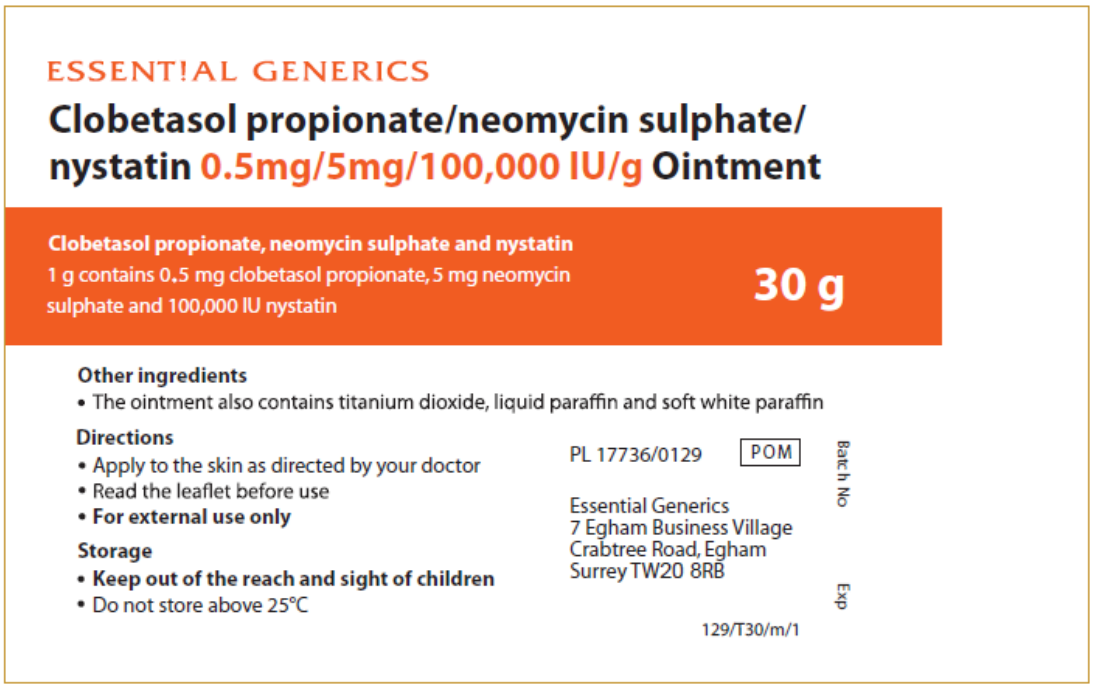
0.5mg/5mg/100,000 IU/g Ointment
Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RB
30 g
ESSENTIAL GENERICS
Clobetasol propionate/ neomycin sulphate/nystatin 0.5mg/5mg/100,000 IU/g Ointment
30 g
Ingredients
• Each 1 g contains 0.5 mg clobetasol propionate (0.05 % w/w), 5 mg neomycin sulphate (0.5 % w/w) and 100,000 IU nystatin
• It also contains titanium dioxide, liquid paraffin and soft white paraffin
PL 17736/0129
POM
Directions
• Apply to the skin as directed by your doctor
• Read the enclosed leaflet before use
• Break the tube seal using the cap
• For external use only
Storage
• Keep out of the reach and sight of children
• Do not store above 25°C


ESSENTIAL GENERICS
Clobetasol propionate/neomycin sulphate/nystatin 0.5mg/5mg/100,000 IU/g Ointment
Clobetasol propionate, neomycin sulphate and nystatin
1 g contains 0.5 mg clobetasol propionate, 5 mg neomycin sulphate and 100,000 IU nystatin
30 g
Other ingredients
• The ointment also contains titanium dioxide, liquid paraffin and soft white paraffin
Directions
• Apply to the skin as directed by your doctor
• Read the leaflet before use
• For external use only
Storage
• Keep out of the reach and sight of children
• Do not store above 25°C
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