

**Public Assessment Report**

**UKPAR**

**Prescription Only to Pharmacy Reclassification**

**Dovonex Psoriasis 50 microgram/g Ointment**

**Calcipotriol**

**PL 00043/0219-0001**

**Leo Laboratories Limited**

**PUBLIC ASSESSMENT REPORT**

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## 1. Introduction

Dovonex Psoriasis 50 microgram/g Ointment (hereafter called Dovonex Psoriasis) is a medicine to be applied to the skin to treat mild to moderate plaque psoriasis which has been previously diagnosed by a doctor, for adults aged 18 years and over, for use for a period of not more than 12 weeks.

The Licence holder, Leo Laboratories Limited, applied to make this product available as a Pharmacy (P) medicine, for sale in pharmacies, by or under the supervision of a pharmacist.

The Medicines and Healthcare Products Regulatory Agency (MHRA) considers this medicine is safe enough to be sold in pharmacies

## 2. Background

The active ingredient in Dovonex Psoriasis (calcipotriol) is one of a group of medicines called vitamin D analogues. When calcipotriol is applied to skin affected by plaque psoriasis, it can help to reduce the number of cells made by the skin, thereby reducing the silver scaly patches and redness associated with psoriasis.

'Dovonex Ointment', containing calcipotriol, was first authorised in the UK as a prescription only medicine (POM) in 1991. In Denmark it was authorised as a prescription medicine in 1990.

'Dovonex Psoriasis' was authorised with pharmacy legal status in Ireland in 2016. This was the first application for pharmacy availability for this product in the UK.

The licence holder intends to keep their existing prescription only (POM) product licence for 'Dovonex Ointment'. This is licensed for the same group of patients as the P product and also for treatment of plaque psoriasis where close medical supervision is considered necessary, for example where disease more extensive and/or severe.

## 3. Proposed Terms of Reclassification

The applicant proposed the following conditions for the availability of Dovonex Psoriasis through Pharmacies:

- topical use (application to the skin)
- treatment of mild to moderate plaque psoriasis which has been previously diagnosed by a doctor in adults aged 18 years of age and over
- application once daily
- maximum weekly dose: 60g ointment
- maximum duration of use: 12 weeks
- pack size: 60g ointment

## 4. Criteria for P classification

To be reclassified from POM to P, a medicine must:

- Be unlikely to be a direct or indirect danger to human health when used without the supervision of a doctor, even if used correctly
- Be generally used correctly (ie not frequently or to a wide extent used incorrectly)
- Not contain substances or preparations of substances where the activity of the product or its side effects require further investigation
- Not normally be prescribed by a doctor for injection (parenteral administration)

These criteria are set out in the Human Medicines Regulations 2012, Regulation 62(3).

## **5. Assessment of suitability for pharmacy availability**

### **5.1 Prescription Only Criteria**

The MHRA assessed the application against the criteria for classification as a Prescription Only Medicine, as stated in section 4.

#### **5.1.1 Direct danger**

Direct danger means that a danger may be present if the product causes adverse reactions that are important.

The most frequently reported adverse effects during treatment with calcipotriol are skin reactions such as pruritis (itchiness), skin irritation and erythema (redness of the skin). Systemic reactions (reactions which occur when calcipotriol is absorbed across the skin and into the bloodstream) such as hypercalcaemia have been reported.

An important risk with the use of calcipotriol, the active ingredient in Dovonex Psoriasis without medical supervision is that of developing hypercalcaemia (excessive levels of calcium in the blood). Calcipotriol has an effect on how the body deals with calcium, and if absorbed through the skin into the bloodstream has the potential to cause hypercalcaemia, although this is rare.

The risk of hypercalcaemia may be increased if the product is used incorrectly, for example by excessive application (over large areas of skin or application too frequently) or by application under occlusion (under a dressing or plaster). The risk increases if more than 100g ointment is applied in any one week.

The risk of developing hypercalcaemia when using Dovonex Psoriasis is minimised by the following conditions of the marketing authorisation:

- Restriction of the indication for the product to adults with mild to moderate plaque psoriasis. Mild to moderate plaque psoriasis is limited to the patient's trunk and/or limbs and covers <10% of their skin surface area (as a guide, the skin surface area of an arm is approximately 9%)
- Limiting frequency of application to once-daily.
- Limiting the amount which may be applied in a week to 60g of ointment

These conditions of use are communicated to the patient via the patient information leaflet and packaging. The patient information leaflet states the signs of hypercalcaemia and advises the patient to stop using Dovonex Psoriasis and see their doctor straight away if they notice any such signs. The patient information leaflet also advises the patient not to use the ointment under occlusion (under a dressing or plaster).

There is the potential risk that calcipotriol may increase the effect of UV radiation which could cause skin tumours. There is a warning with this product for patients to limit or avoid excessive exposure to either natural or artificial sunlight. This warning is communicated to the patient on the packaging and in the patient information leaflet.

Dovonex Psoriasis Ointment is intended for use on the skin and, with the exception of emollients (moisturisers), without combination with other topical preparations for psoriasis. There is no evidence of interaction of calcipotriol with other drugs or food and risk of significant drug interactions for the ointment is negligible based on minimal systemic absorption (absorption across the skin into the bloodstream) of calcipotriol. The danger of interactions leading to adverse effects is low for this product.

### **5.1.2 Indirect danger**

Indirect danger to human health, even when the product is used correctly, could occur where treatment might mask or hide an underlying condition requiring medical attention and supervision. Use of the medicine might delay diagnosis and definitive treatment and jeopardise the chance of more successful therapy. Therefore, it is important that the condition or symptoms for which a medicinal product not subject to a medical prescription is indicated, can be correctly assessed by the patient and that the product can be used without medical supervision.

Dovonex Psoriasis is indicated for plaque psoriasis which has been previously diagnosed by a doctor and therefore, patients wishing to purchase this product from a pharmacy will be aware of their condition. Since plaque psoriasis is a chronic, recurring condition, patients will be familiar with flare-ups and the need to get suitable treatment.

The patient must speak to their doctor if they have psoriasis covering a large area of the body, psoriasis with pus-filled bumps, if their joints swell or are painful or if they have problems with their nails. These other forms of psoriasis or complications of psoriasis, require treatment under medical supervision. Dovonex Psoriasis, purchased from a pharmacy, would not be suitable in such cases. Dovonex Psoriasis should not be applied to the face, scalp, genital area or skin folds since treatment of these areas requires medical supervision. This information is communicated to the patient in the patient information leaflet and on the label.

The patient is instructed, via the label and leaflet, to stop using Dovonex Psoriasis and seek medical advice if their psoriasis becomes worse at any time or is no better after using the ointment every day for 4 weeks. The patient is also advised in the patient information leaflet to see their doctor if they feel their psoriasis has not cleared up by up to 50% after using the medicine for 12 weeks.

Pharmacists and their staff will be provided with training material which will enable them to provide suitable advice to the patient and help the patient decide if Dovonex Psoriasis is suitable for them. The product outer packaging and the patient information leaflet also include an image of plaque psoriasis which will facilitate both pharmacists and patients in this respect.

There is potential for patients with previous experience of using the prescription product (Dovonex Ointment) twice-daily, to inadvertently or deliberately use the pharmacy product twice daily, instead of once daily as recommended for the pharmacy product. Pharmacy training materials will specifically include a prompt for the pharmacist to ask patients if they have used Dovonex Ointment previously, and if so at what frequency. The once-daily dosage of Dovonex Psoriasis will be emphasised by the pharmacist, with patients advised to seek medical advice if they need to use the product twice daily.

Dovonex Psoriasis is contraindicated (not recommended for use) in patients who are pregnant or breast-feeding unless under supervision of a doctor. Patients are advised via the label and leaflet not to use Dovonex Psoriasis Ointment and to speak to their doctor if they are pregnant or breast-feeding.

Dovonex Psoriasis is intended for topical use (use on the skin) and, with exception of emollients, without combination with other topical preparations for psoriasis. There is a risk that patients may use topical corticosteroids at the same time as Dovonex Psoriasis. Many patients with psoriasis may have received such treatment previously under supervision of a doctor and may have corticosteroid preparations available to use. In addition, low potency topical corticosteroids are

available from pharmacies without prescription. The patient information leaflet and label give clear instructions to the patient not to use any other psoriasis treatment, other than an emollient (moisturiser), while using Dovonex Psoriasis.

### **5.1.3 Incorrect use – frequently and to a very wide extent**

From data available, there is no evidence that the prescription product (Dovonex Ointment) is known to be frequently and to a very wide extent used incorrectly. Calcipotriol is not considered to be a compound associated with abuse or addiction potential and there is no known illicit use of topical calcipotriol. Incorrect use of the pharmacy product Dovonex Psoriasis, frequently and to a very wide extent would therefore not be expected, nor would abuse of the product.

### **5.1.4 Activity and/or adverse reactions require further investigation**

This product has been used as a prescription product since 1991 and the activity and adverse reactions are well established. Therefore, this criterion does not apply.

### **5.1.5 Is normally prescribed as an injection**

This product is for application to the skin only, so this does not apply.

## **5.2 Risk Management Plan**

The application included a risk management plan (RMP). RMPs are documents that contain information on a medicine's safety profile and one or more of the following:

- How any risks identified in the safety profile will be prevented or minimised in patients
- Plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine
- Risk factors for side effects
- Measuring the effectiveness of measures taken to prevent or minimise risks.

The RMP for this product identified the main risks associated with the product and proposed how these will be managed in the product information (Summary of Product Characteristics, labelling and patient information leaflet) and by the provision of training material for pharmacists and their staff.

### **5.2.1 Training resources**

Additional resources will be provided for pharmacists, which cover the following topics:

- pathophysiology of psoriasis and mechanism of action of Dovonex Psoriasis and other preparations used to treat mild to moderate plaque psoriasis
- clinical presentation of mild to moderate plaque psoriasis suitable for treatment with Dovonex Psoriasis and recognition of patterns of disease and severity of disease suitable for such treatment
- recognition of types of psoriasis other than plaque psoriasis (eg. guttate, pustular) which are unsuitable for self-management without a doctor's supervision
- recognition of the development of erythrodermic psoriasis as a medical emergency, in the unlikely event that a person with this serious condition will present to pharmacy
- recommending Dovonex Psoriasis appropriately in line with the conditions stated in the marketing authorisation (indications, contraindications etc)
- advising patients in the correct use of the product, pattern of response including when to continue or discontinue treatment, recognition of adverse events and when to refer to doctor
- recognising the signs and symptoms of disease progression

- appropriate pharmacy counter staff training

## 6. Advice from the Commission on Human Medicines

The Commission on Human Medicines (CHM) advised in favour of Pharmacy availability of Dovonex Psoriasis 50 microgram/g Ointment for treatment of mild to moderate plaque psoriasis which has been previously diagnosed by a doctor in adults aged 18 years and over, for application once daily, with maximum duration of use of 12 weeks and maximum pack size of 60g of ointment. Views on the use of this medicine in practice under the proposed conditions were also sought at an ad hoc stakeholder group meeting, held under auspices of CHM. The members of the group consisted of healthcare professionals and patients affected by psoriasis. The views of the stakeholder group were summarised in a report which was considered by CHM.

## 7. Consultation on Pharmacy Availability of Dovonex Psoriasis

Consultation ARM 95 proposing pharmacy availability of Dovonex Psoriasis was issued on 30 March 2017 with a deadline for comments of 20 April 2017. A copy of the consultation document and details of the responses are available on the MHRA website.

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/604680/Dovonex\\_psoriasis\\_public\\_consultation\\_final.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/604680/Dovonex_psoriasis_public_consultation_final.pdf)

## 8. Responses to consultation ARM 95

There were 14 responses received, 12 in favour and 2 against. 4 respondents requested that their response remain confidential and 1 partially confidential. Of the 12 responses in favour, 6 were from professional organisations (3 medical, 3 pharmacy), 1 from a patient organisation, 3 from pharmacists and 2 from patients with psoriasis. Of the 2 responses against, 1 was from a patient association and 1 from a patient with psoriasis.

The responses provided have not raised any new safety concerns with respect to reclassification of Dovonex Psoriasis as a pharmacy (P) medicine.

The following is a summary of the key issues raised and how they have been addressed:

### ***Patient information leaflet should say that Dovonex is only for adult use.***

The patient information leaflet (section 1) includes bold sub-heading 'This medicine is used in adults to treat...'. and in section 2 under bold sub-heading 'Children and adolescents' also clarifies that 'Dovonex psoriasis is only suitable for use in adults over 18 years old'. The label outer carton also clearly states that 'This medicine is suitable if you are 18 years and older' (side of pack) and 'Topical treatment for adults previously diagnosed with mild to moderate plaque psoriasis' (front of pack).

### ***Availability of Dovonex Cream***

The product licence for Dovonex Cream was cancelled on 2/4/2013 and is therefore no longer available as a prescription only medicine (POM). Dovonex Ointment however, will still be available as a POM.

### ***Information about possible photosensitivity and the risks of that, are not made clear in the patient information.***

### ***Important not to raise patient anxiety regarding risk of skin cancer when using the product***

The active ingredient in Dovonex Psoriasis (calcipotriol) is for application to the skin and can rarely cause photosensitivity reactions (enhance the harmful effects of the sun). To address this concern the

patient information leaflet has been updated to not only state that the patient should avoid sunbathing or using sunbeds while using Dovonex Psoriasis, but also to state the reasons why. These amendments made to the patient information provide further information concerning photosensitivity, while at the same time not causing undue anxiety regarding risk of skin cancer when using the product.

The labelling also advises the patient to 'Avoid excessive exposure to natural or artificial sunlight eg. Sunbathing and sun beds, while using this medicine'.

### ***Once daily application verses twice daily application for the prescription only product***

The issue of once daily application for the pharmacy product was considered by the ad hoc stakeholder group and CHM. The licensed prescription only (POM) product (Dovonex Ointment) is approved for once or twice daily application. Clinical studies clearly demonstrate efficacy of once daily application of the ointment. Experience of patients using the product was that once daily use was preferred to twice daily.

The patient information leaflet for Dovonex Psoriasis states that the ointment should be applied once daily. The pharmacy training materials include a prompt for the pharmacist to establish if the patient has used Dovonex Ointment before and if so, at what frequency. If it is established that the patient requires twice daily application of ointment to control their psoriasis, the training material will advise the pharmacist to refer the patient back to their doctor for review. It was considered therefore that licensing Dovonex Psoriasis for once daily application only was acceptable.

### ***Inappropriate use, for example without appropriate diagnosis, or excessive use over larger areas of skin.***

These issues were considered by the ad hoc stakeholder group and CHM. The patient information leaflet states that the product is for use in adult patients with mild to moderate plaque psoriasis which has previously been prescribed by a doctor and gives clear instructions regarding how to apply the product and how frequently. The maximum amount of product (60g ointment) which may be used in any one week is also clearly communicated to the patient. Furthermore, the pharmacist will be available to advise the patient as to whether or not the product is suitable for them.

### ***Over time, lack of medical intervention from a GP and the missed opportunity for referral to specialist services***

This issue was considered by the ad hoc stakeholder group and CHM. The patient information leaflet and labelling both clearly state that 'patients with psoriasis should see their doctor once a year for review'.

### ***The inclusion of the disease name (psoriasis) in the product name of the pharmacy product.***

The name 'Dovonex Psoriasis' is distinct from that of the prescription (POM) product 'Dovonex'. The marketing authorisations (approved conditions of use) for the two products differ, so they cannot share the same name.

### ***Use of 'Dovonex Psoriasis' as opposed to 'Dovonex Psoriasis Ointment' throughout the patient information leaflet.***

Use of the abridged name 'Dovonex Psoriasis' in the patient information leaflet is acceptable in order to avoid repeating the full product name each and every time it is referred to in the leaflet. In order to

avoid excessive use of the brand name, the leaflet also uses 'this medicine' to replace 'Dovonex Psoriasis'. As there are no other pharmaceutical forms available OTC (without prescription) containing the active ingredient calcipotriol, specifying 'ointment' is not necessary. The head of the leaflet and labelling clearly state the full product name, form and strength.

**Availability of Dovonex Psoriasis as a pharmacy product represents a change to recommendations in NICE clinical guideline\* which as first line treatment\*\* recommends use of a potent corticosteroid and vitamin D analogue such as calcipotriol.**

\*NICE (National Institute for Health and Clinical Excellence) is part of the NHS and is the independent organisation responsible for providing national guidance on treatments and care for people using the NHS in England and Wales. NICE Clinical Guidelines recommend how healthcare professionals should care for people with specific conditions.

\*\* First-line treatment is the preferred, standard or first choice treatment for a disease/condition.

The pharmacy product Dovonex Psoriasis is not intended as a first line treatment. It is for use by adults with mild to moderate cases of plaque psoriasis which have been previously diagnosed by a doctor.

The decision about first line treatment will continue to be made by the doctor.

***Ability of pharmacists to recognise and offer appropriate management advice to patients regarding skin problems, including psoriasis.***

This issue was addressed during assessment of the application and was considered by the ad hoc stakeholder group and by CHM. Pharmacists are already providing advice to patients with psoriasis, so the disease area is not new to them. Pharmacists and their staff will be provided with training material which will enable them to provide suitable advice to the patient and help the patient decide if Dovonex Psoriasis is suitable for them.

***The use of percentages in the patient information leaflet which may lead to confusion in those seeking to use the product. For example, 'You must see your doctor if you feel that your psoriasis has not cleared by up to 50% after using this medicine for 12 weeks' and 'You should only use this product to treat total area of skin no bigger than the skin surface of one of your arms (around 10% of your body surface area)'.***

The content of the patient information leaflet must reflect the information stated in the product marketing authorisation. As part of the reclassification application, user testing data for the leaflet was submitted and considered to be acceptable. It was demonstrated that patients could understand and act upon information provided in the leaflet.

***The supply of Dovonex Psoriasis will always require the intervention of a pharmacist and not be delegated to members of the pharmacy team.***

. As a product with pharmacy legal status, Dovonex Psoriasis must be supplied by, or under supervision of, a pharmacist. Whether the supply is undertaken personally by the pharmacist or delegated to members of the pharmacy team is a professional decision to be taken by the pharmacist.

***Advice in leaflet regarding use of the ointment on the face and advice regarding excess calcium in the blood.***



The patient information leaflet specifies that the product should not be used on the face, but does not specifically exclude the neck and ears. This reflects the information stated in the product marketing authorisation. With respect to excess calcium in the blood, the patient information leaflet specifies that if the patient notices any signs of hypercalcaemia, they will need to stop using Dovonex Psoriasis and see their doctor immediately for assessment. If they seek the advice of the pharmacist first, they will in any case be referred to their doctor. In specifying that the patient should see their doctor, emphasis is made of the fact that hypercalcaemia is a condition which, when it occurs, must be assessed and reviewed by the patient's doctor.

***Limit on quantity that may be supplied at any one time.***

The maximum pack size of product available is 60g of ointment. The pharmacist would supply one tube of ointment to the patient if appropriate. If a patient's condition was improving and they required further supply of ointment, they would need to see their pharmacist. This would provide the opportunity for the pharmacist to reassess suitability of the ointment and provide further advice to the patient regarding treatment of their psoriasis.

***Suitability of use of the ointment on cracked or open skin.***

If the patient's skin becomes cracked or open, this would indicate a worsening of their condition and the need to be referred to their doctor for assessment. Cracked or open skin will also potentially increase the systemic absorption (absorption across the skin and into the bloodstream) of calcipotriol and therefore increase the risk of adverse effects such as hypercalcaemia.

***Cost of the ointment when purchased in the pharmacy, particularly for those patients who do not pay the prescription charge***

The issue of pricing and cost of Dovonex Psoriasis falls outside the scope of MHRA assessment.

## **9. Conclusion**

Assessment of the responses to consultation on the application for Dovonex Psoriasis 50 microgram/g Ointment has revealed no new issues of concern in addition to those considered by CHM and on which CHM were reassured. Considering the advice from CHM, the Licensing Authority has taken the decision to approve Pharmacy legal status for Dovonex Psoriasis 50 microgram/g Ointment.

### **Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling**

In accordance with Directive 2010/84/EU the Summary of Product Characteristics (SmPC) and package leaflet for the product granted a Marketing Authorisation at a national level is available on the MHRA website.

The approved labelling for Dovonex Psoriasis is presented below:

**Medicines and Healthcare Products Regulatory Agency  
August 2017**

No varnish



# Dovonex<sup>®</sup>

## PSORIASIS 50 microgram/g ointment

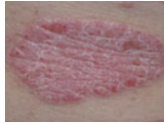
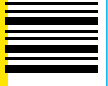
### calcipotriol

- ▶ Topical treatment for adults previously diagnosed with mild to moderate plaque psoriasis
- ▶ Patients with psoriasis should see their doctor once a year for review

**Dovonex<sup>®</sup>**  
PSORIASIS 50 mcg/g ointment  
calcipotriol

**60 g**

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#### WHAT IS PLAQUE PSORIASIS?

Plaque psoriasis is a condition where your skin develops raised red patches and silver coloured scaly patches.

#### THIS MEDICINE IS SUITABLE IF:

- You are 18 years or older.
- A doctor has diagnosed plaque psoriasis in the past and your skin symptoms have not changed.
- Your psoriasis affects the skin on your body or limbs.

#### DO NOT USE THIS MEDICINE AND SEE YOUR DOCTOR IF YOU:

- Have an allergy to any ingredient listed on this pack.
- Are pregnant, or think you might be pregnant, or are planning to have a baby, or breast-feeding.
- Have a problem with how your body handles calcium.
- Have problems with your liver or kidneys.
- Have psoriasis on your face, genitals, scalp or skin folds.
- Have psoriasis affecting more than 10% of your body surface (about the area of skin on one arm).
- Have painful joints or nail problems.

LEO

# Dovonex<sup>®</sup>

## PSORIASIS 50 microgram/g ointment

### calcipotriol

**60 g**

Read the package leaflet before use.  
For application to the skin.

#### HOW TO USE THIS MEDICINE

- ▶ Wash your hands before and after use.
- ▶ Apply a layer of this ointment to the affected area once a day and rub in gently.
- ▶ A maximum weekly dose should not exceed 60 grams.

#### YOUR PSORIASIS SHOULD START TO IMPROVE WITHIN 4 WEEKS.

See your doctor:

- ▶ If no improvement is seen after 4 weeks of treatment.
- ▶ If your psoriasis changes or worsens.
- ▶ If you get any signs of an increased blood calcium level (see leaflet for further information).

Lot  
EXP

#### IMPORTANT INFORMATION

Use this medicine on your skin only.  
Contains propylene glycol. It may irritate your skin.  
See leaflet for further information.  
Keep out of the sight and reach of children.  
Avoid excessive exposure to natural or artificial sunlight, e.g. sunbathing and sun beds, while you are using this medicine.  
You should not use any other psoriasis treatment other than a moisturiser (emollient) while you are using this medicine.

Do not store above 25°C.

**Contains:**  
calcipotriol 50 microgram/g

**Other ingredients:**  
disodium edetate, disodium phosphate dihydrate, all-*rac*- $\alpha$ -tocopherol, liquid paraffin, macrogol-(2)-stearyl ether, propylene glycol, purified water, white soft paraffin.

Date opened: \_\_\_\_\_ Discard the tube 6 months after first opening.

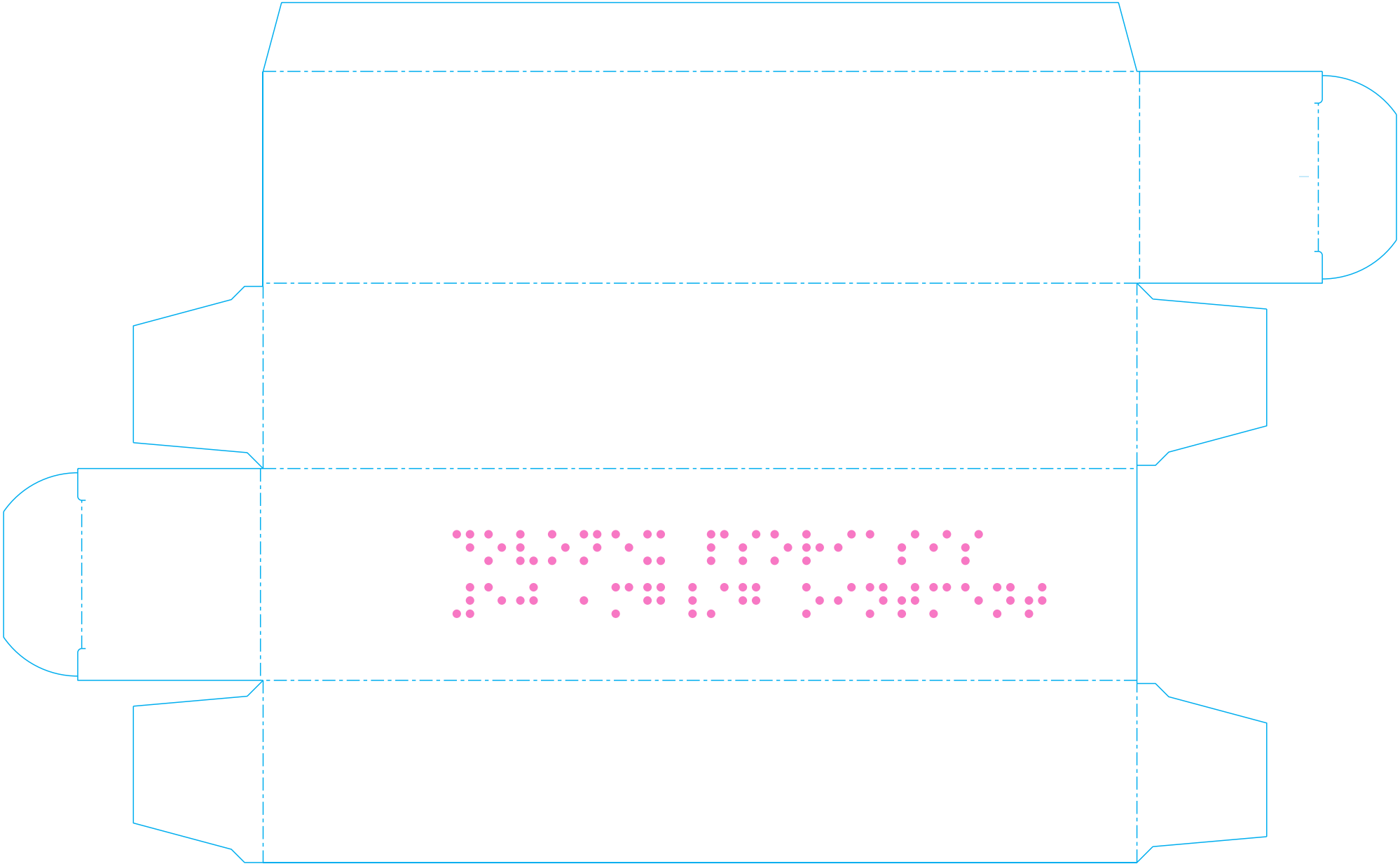
LEO Laboratories Limited  
Hurley, Berkshire  
SL6 6RJ, UK

PL 00043/0219

**P**



40 x 35 x 165  
CIE034-03



WELCOME TO THE  
WORLD OF

# Dovonex<sup>®</sup>

## PSORIASIS 50 microgram/g ointment

### calcipotriol

**60 g**

Topical treatment for adults  
previously diagnosed with mild  
to moderate plaque psoriasis

Contains: calcipotriol 50 microgram/g

**Read the package leaflet before use.**

For application to the skin.

#### IMPORTANT INFORMATION

Keep out of the sight and reach of children.

Do not store above 25°C.

Discard the tube 6 months after first opening.

LEO Laboratories Limited  
Hurley, Berkshire SL6 6RJ, UK

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#### HOW TO USE THIS MEDICINE

- ▶ Wash hands before and after use.
- ▶ Apply a layer of ointment to the affected area once a day and rub in gently.
- ▶ A maximum weekly dose should not exceed 60 grams.

#### Other ingredients:

disodium edetate, disodium phosphate dihydrate, all-*rac*- $\alpha$ -tocopherol, liquid paraffin, macrogol-(2)-stearyl ether, propylene glycol, purified water, white soft paraffin.

See leaflet for further information.

**P**

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