Guidance on the Safe Supply of Dovonex® Psoriasis Ointment by Pharmacists

Pharmaceutical Society of Ireland

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Contents

1. Introduction

Dovonex® Psoriasis (calcipotriol 50 microgram/g) ointment, is licensed as a pharmacy only medicine for the treatment of adults with mild to moderate plaque psoriasis which has been previously diagnosed by a doctor.

The purpose of this guidance is to assist pharmacists in the safe supply of Dovonex® Psoriasis ointment, in line with the product's marketing authorisation. Due to the need to confirm the patient's diagnosis of plaque psoriasis and the counselling requirements for the appropriate use of this product, Dovonex® Psoriasis ointment must only be supplied by the pharmacist.

2. Guidance

The supply of Dovonex® Psoriasis ointment must only be made by a pharmacist following a structured consultation with the patient. Each time this medicine is supplied the pharmacist must be satisfied that, in the exercise of his or her professional judgment, the supply of such a medicine is safe and appropriate for the individual patient.

In order to determine the appropriateness of the supply, the pharmacist should be familiar with the information in the product's Summary of Product Characteristics (SmPC) which is available on the Health Products Regulatory Authority's (HPRA) website (www.hpra.ie). This includes the therapeutic indications, contraindications, special warnings, precautions for use and interactions.

The supply of non-prescription medicines by a pharmacist must also comply with Regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), which states that, in relation to the sale or supply of any non-prescription medicine, a registered pharmacist must be satisfied that the purchaser is aware of the appropriate use of the medicine, that it is being sought for that purpose and that it is not intended for abuse and/or misuse. In order to facilitate the safe use of Dovonex® Psoriasis ointment, pharmacists should consider making a record of the supply, for example in the Patient Medication Record (PMR).

2.1 Therapeutic Indication and Dose

- Dovonex® Psoriasis ointment is indicated for the treatment of adults, aged 18 years and over, with mild to moderate[1] plaque psoriasis which has been previously diagnosed by a doctor.
- It should be applied to the affected area (trunk and limbs only) once daily.
- Maximum weekly usage should not exceed 100g (one tube contains 60g). It is recommended that patients who require more than 100g per week are referred to their doctor.
- Dovonex® Psoriasis ointment, should NOT be supplied for use on children and adolescents aged less than 18 years. There is an increased risk of hypercalcaemia in this age-group and therefore supervision by a doctor is needed.

2.2 Contraindications and Warnings

Dovonex® Psoriasis ointment is contraindicated in the following situations; these patients should be referred to a doctor:

- Women who are pregnant or breast feeding, or planning to become pregnant.
- Hypersensitivity to the active substance or to any of the excipients.
- Known disorders of calcium metabolism.
- Severe liver and kidney disease (due to lack of data).
- Psoriatic arthritis or nail involvement.

2.3 Interactions

Dovonex® Psoriasis ointment should not be used concurrently with calcium or vitamin D supplements, or drugs which enhance the systemic availability of calcium.

2.4 Adverse Reactions

- Pruritus, skin irritation and erythema are the most frequently reported adverse reactions during treatment.
- Systemic reactions (hypercalcaemia and hypercalciuria) have been reported. The risk of developing such reactions increases if the maximum weekly dose of 100g is exceeded.

2.4.1 Signs and Symptoms of Hypercalcaemia

Pharmacists should be alert to signs and symptoms of hypercalcaemia which can occur if the maximum weekly dose is exceeded (due to the content of calcipotriol). If the patient presents with any of the symptoms listed below, the patient should be advised to stop treatment and see their doctor immediately. Signs and symptoms of hypercalcaemia can include:

- Excessive thirst, frequent urination, stomach upset, nausea, vomiting, constipation, muscle weakness, bone pain, confusion, coma, fatigue or lethargy.

[1] This condition is said to be mild to moderate when the area affected does not exceed 10% of body surface area (for guidance purposes, the body surface area of an arm is approximately 9%).

3. Patient Counselling

The supply of non-prescription Dovonex® Psoriasis ointment must only be carried out by the pharmacist, who must confirm that the patient has plaque psoriasis (as distinct from a different form of psoriasis or skin condition), previously diagnosed by a doctor.

If a supply is deemed appropriate, patient counselling should include information and advice on the following:

- The correct application of Dovonex® Psoriasis ointment, highlighting that it should not be applied to the face, scalp, flexures or genital area, and not just before a shower or bath. The patient should be advised to wash their hands after application to avoid accidental transfer to the face and eyes.
- Emollients may be used alongside treatment or it may be used as a monotherapy.
- To not exceed the maximum weekly usage of 100g, or cover Dovonex® Psoriasis ointment with any type of occlusive bandage, as this may increase the risk of hypercalcaemia.
- To see a doctor if the condition does not start to improve within 4 weeks of treatment, becomes worse at any time during treatment, they develop more extensive skin or nail involvement, or they develop joint pains and/or swelling of joints.
- To avoid excessive exposure to either natural or artificial sunlight and avoid the use of UV lamps during treatment.
- If within 12 weeks the condition has cleared or is substantially improved and the patient is satisfied with the outcome, the treatment can be stopped. The treatment can be re-started if psoriasis reappears.
- If a patient does not reach a satisfactory outcome (e.g. achieves less than 50% reduction in psoriasis) by 12 weeks, the patient should be referred to a doctor for review.
- If the patient is using other psoriasis treatments, such as other topical products containing calcipotriol, topical corticosteroids, topical retinoids, calcineurin inhibitors or systemic anti-psoriatic therapies, this product should only be used under the advice and supervision of a doctor.
- A review of the patient's condition, by a doctor, should be done at least once a year.
- Dovonex® Psoriasis ointment is licensed to treat plaque psoriasis only, it should not be used on other forms of psoriasis, except under the supervision of a doctor.

4. Storage of Dovonex® Psoriasis Ointment

Due to the requirement for the pharmacist to be directly involved in the decision to supply this medicine, the pharmacist must store Dovonex® Psoriasis ointment in the dispensary under their direct control and supervision.

5. Pharmacovigilance

Any suspected adverse reactions should be reported to the HPRA using the online Human Medicines Adverse Reaction Report system at www.hpra.ie, by telephone: +353 1 676 4971, by email: medsafety@hpra.ie or by obtaining a Yellow Card from the HPRA and returning it to: Pharmacovigilance, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2.

6. Policies and Procedures

Superintendent and supervising pharmacists must ensure that documented policies and procedures are in place, which address the supply of Dovonex® Psoriasis ointment, in the pharmacies under their control. These documents should address all issues identified in this guidance and be reviewed and updated in line with further guidance or any other relevant information in this area. Superintendent and supervising pharmacists must ensure that there is adequate staff training in place to ensure compliance with policies and procedures and all staff are aware that they must refer requests for Dovonex® Psoriasis ointment to the pharmacist.

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7. Self-Assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with this guidance and to assist superintendent and supervising pharmacists in drawing up the relevant policies and procedures. The checklist captures many important elements of the guidance; it is not exhaustive and should only be used to assess pharmacy practice in combination with this guidance and all other relevant guidance and requirements.

Ask Yourself	Yes	No	N/A	Required Action
Is the pharmacist and all relevant staff members aware of the licensed indications for Dovonex® Psoriasis ointment?				
Are members of staff aware that all requests for Dovonex® Psoriasis ointment must be referred to the pharmacist?				
Does the pharmacist carry out a thorough consultation with each patient to determine if Dovonex® Psoriasis ointment is safe and suitable for them to use?				
Does the pharmacist counsel the patient to ensure that they know how to safely use this product and are aware of the maximum weekly usage?				
Is Dovonex® Psoriasis ointment stored in the dispensary under the direct control and supervision of the pharmacist?				
Are there written policies and procedures in place for all aspects of the supply of Dovonex® Psoriasis ointment?				
Is the superintendent pharmacist and supervising pharmacist satisfied that all pharmacists practising in the pharmacy, and relevant staff members, are trained on, and following, the relevant policies and procedures?				