



28<sup>th</sup> February 2019

Circular 002/19

**Re: Dimethyl Fumarate (Skilarence)**

Dear Pharmacist,

Skilarence® (dimethyl fumarate) is a newly approved High Tech medicine for the treatment of moderate to severe plaque psoriasis in adults and will be reimbursed from 1<sup>st</sup> February 2019. Dimethyl fumarate is currently available for this indication as the exempt medicinal product, Fumaderm® (fumaric acid derivatives) and is reimbursed on an individual patient basis. I refer to Circular 024/17 in this regard.

From 1<sup>st</sup> February, applications for newly initiated patients will require the completion of an individual reimbursement form specific to Skilarence®. Applications must be completed by the Consultant Dermatologist responsible for the management of the patient's psoriasis. I enclose a copy of the application form with this Circular. Patients who have prior approval for Fumaderm® will continue to have seamless access to this product for a period of 4 months (February- May 2019 inclusive). However, after this period the patient should have transitioned to the licensed medicine.

You are reminded that Skilarence® is a High Tech medicine and a High Tech prescription must be issued when patients are initiated or transitioned to this product. A patient care fee will not be paid in the absence of prior approval.

Code	Product Description	Reimbursement Price
<b>88933</b>	Skilarence Gastro Resistant Tabs. 30 mg (42)	€90.72
<b>88934</b>	Skilarence Gastro Resistant Tabs. 120 mg (90)	€202.18
<b>88935</b>	Skilarence Gastro Resistant Tabs. 120 mg (180)	€404.35

In addition, Tecfidera® (dimethyl fumarate) is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis. It is available in presentations of 120 mg (14 Caps) and 240 mg (56 Caps). High Tech claims in respect of this medicine will be monitored to ensure that they are submitted in accordance with the licensed indication.

Given the significant cost of Skilarence®, we appreciate your co-operation with this matter.

Yours faithfully,

Anne Marie Hoey  
Primary Care Reimbursement and Eligibility

**CONFIDENTIAL**

<i>For PCRS Use Only</i>	
<i>Case Reference</i>	<i>Date Received</i>

**Application for individual reimbursement of Skilarence® (dimethyl fumarate) by Consultant Dermatologists**

In order to authorise reimbursement of this medicine on the **High Tech Drug Scheme (HTDS)** the prescribing consultant must provide the following information and submit to the Primary Care Reimbursement Service (PCRS) for approval prior to initiating treatment.

Skilarence® is indicated for the treatment of moderate to severe plaque psoriasis in adults in need of systemic medicinal therapy and is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of psoriasis.

Date of Application		Nominated Pharmacy	
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**1. Patient Details**

Name			
Date of birth			
Address			
GMS / DPS / PPS Number (Please tick and insert number)	Number:		
	GMS	DPS	PPSN

**2. Prescriber details**

Name of Consultant dermatologist	
Medical council number	
Contact Details:	Address:
	Telephone:
	Email:

**3. Diagnosis**

Please tick to confirm

**This patient has moderate-severe psoriasis which, in my opinion, requires systemic treatment**

**This patient meets the clinical criteria and screening for dimethyl fumarate**

#### 4. Previous treatments used for this condition to date

1.	
2.	
3.	
4.	

#### 5. Recommended treatment protocol

Weeks 1-3: Tolerability-improving pre-treatment (30mg OD → 30mg BD → 30mg TDS)

Weeks 4-9: Up titration subject to individual tolerability (120mg OD→BD→TDS further increased on a weekly basis as needed up to a maximum of 240mg [2 x 120mg] TDS)

Please tick to confirm

**This patient will be treated as per protocol (above) and to a maximum dose of 240mg three times daily (only doses up to 240mg three times daily will be reimbursed)**

Note:

- *Once psoriasis has cleared, the dose should be gradually reduced to the **lowest possible dose** that keeps it clear.*

#### Authorisation of request

Signature of <b>prescribing</b> consultant	
Institution	

**Completed forms should be submitted to:**

Kate Mulvenna MPSI  
Head of Pharmacy Function  
Primary Care Reimbursement Service  
Exit 5, M50, North Road,  
Finglas, Dublin 11  
Phone: 01-8647100  
Fax: 01-8647142