Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5 an M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Guthán: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

26th May 2017

Circular 024/17

Fumaderm® Initial 30 mg and Full Strength 120 mg (Exempt Medicinal Product)

Dear Pharmacist,

You will be aware from recent communication (Circular 039/16) that Fumaderm® (Fumaric Acid derivatives) was reviewed by the Medicines Management Programme to examine the clinical requirements for this exempt medicinal product. Following this review, existing patients (prior to 1st September 2016) will continue to receive reimbursement support.

In future, applications for newly initiated patients will require the completion of an individual reimbursement form specific to Fumaderm®. Patients will be required to nominate a pharmacy of choice for dispensing of Fumaderm®. Applications must be completed by the Consultant Dermatologist responsible for the management of the patient's psoriasis. In addition, a copy of the prescription must accompany applications. Approval will not be forthcoming in the absence of confirmation of Hospital Initiation.

Enclosed is a copy of:

- Application for individual reimbursement of Fumaderm® (unlicensed) by Consultant Dermatologist
- Information for pharmacists in relation to individual reimbursement of Fumaderm® (unlicensed) by Consultant Dermatologists developed by the Medicines Management Programme.

From June 1st 2017, pharmacies can dispense and claim Fumaderm® for existing and approved patients electronically using the administration codes enclosed, submitting them in the normal manner with monthly claims. Claims submitted for patients who are not approved will not be paid.

If you have any further queries in relation to the information provided, please contact PCRS.ExemptMed@hse.ie. Exempt medicinal products in Ireland will be subject to an ongoing review with due diligence regarding the unmet clinical need.

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

Yours faithfully,

Anne Marie Hoey

Anne Marie Hoey
Primary Care Reimbursement & Eligibility

Fumaderm® (ULM) - Circular 024/17 (Effective 1st June 2017)

Drug Code	Drug Description including coding instruction	Reimbursement Price €	Supplier
20350	Fumaderm (ULM) Initial Tabs 30 mg 40 (A) Non Proprietary Name: Fumaric Acid Derivatives, Combinations	162.45	Medisource Pharmasource QM Specials IDIS
20351	Fumaderm (ULM) Tabs 120mg 70 (A) Non Proprietary Name: Fumaric Acid Derivatives, Combinations	353.53	Medisource Pharmasource QM Specials IDIS

For PCRS Use Only	
Case Reference	*Date Received*

Application for individual reimbursement of Fumaderm® (unlicensed) by Consultant Dermatologists

In order to approve reimbursement of this medicine, by exceptional arrangements, the prescribing consultant must provide the following information and submit to the Primary Care Reimbursement Service.

Fumaderm® is an unlicensed medicine. Licensed medicines should be used where possible. The patient is aware that this product is unlicensed but I believe this is the best therapeutic option for this patient at this time.

Date of Application		Nominated Pharmacy	

1. Patient Details

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

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 Fumaderm ☐

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) ☐

This patient has been provided with written information regarding Fumaderm ☐

If you intend to use an alternative dosing protocol please outline clearly here:

_____

_____

_____

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 **prescribing** 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

Medicines Management Programme

Information for pharmacists in relation to individual reimbursement of Fumaderm® (unlicensed) prescribed by Consultant Dermatologists

Fumaderm® is an unlicensed medicine and therefore should only be prescribed in cases where no other licensed medicine is suitable. Fumaderm® contains fumaric acid esters (FAEs) and is used to treat moderately severe to severe psoriasis.

In order to approve reimbursement of this medicine, by exceptional arrangements, the prescribing consultant must complete a specific **Fumaderm® Application** and submit it to the Primary Care Reimbursement Service.

When approved, patients who have been prescribed Fumaderm® by a consultant dermatologist , will be eligible for reimbursement of Fumaderm® under the GMS and DP schemes up to the maximum licensed dose (240mg TDS).

Counselling points

- The tablets should be swallowed whole and taken with or after a meal.
- It may take four to six weeks to see a benefit to psoriasis symptoms.
- Side effects include nausea, stomach discomfort, cramps, wind, feeling bloated and diarrhoea. The dose is gradually increased over a number of weeks (see below) to reduce these side effects).
- Regular blood tests are necessary while taking Fumaderm® so ensure patient attends follow-up appointments

Recommended treatment process

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)

Dosage (number of tablets to be taken)				
Week	**Morning**	**Noon**	**Evening**	**FAE formulation**
1	1	-	-	Fumaderm® Initial (white tablet – low strength 30mg)
2	1	-	1	
3	1	1	1	
4	1	-	-	Fumaderm® Full Strength (blue tablet – 120mg)
5	1	-	1	
6	1	1	1	
7	2	1	1	
8	2	1	2	
9	2	2	2	

- *Once psoriasis has cleared, the dose should be gradually reduced to the **lowest possible dose** that keeps it clear.*
- *The maximum dose of 240mg (2 x 120mg) three times daily should not be exceeded and doses above this will not be reimbursed.*