

Taking Fumaderm® (fumaric acid esters) to treat psoriasis

Your doctor has prescribed Fumaderm® for the treatment of your psoriasis. This leaflet explains what it is and what you should know before taking it. If you have any questions or concerns after reading this leaflet, please speak to your dermatology doctor, nurse or pharmacist, who will be happy to help you. Contact details are given at end of this information sheet.

What is Fumaderm® and what is it used for?

Fumaderm®, which contains fumaric acid esters (FAE), is used to treat psoriasis. Taking FAE will not cure your psoriasis, but there should be an improvement, and it may clear completely during treatment. If treatment is stopped however, the psoriasis may be expected to return.

FAE act on cells in the immune system called **T-cells**. T-cells produce chemicals called **cytokines**. A delicate balance of cytokines is needed to maintain health, but for people with psoriasis, this balance is disturbed. FAE change the immune system to reduce the imbalance of the cytokines.

Taking an unlicensed medicine

Fumaderm® is an unlicensed medicine. This means that it does not have a UK product license but is available by special arrangement through our hospital pharmacies. Fumaderm® is licensed and used widely in Germany. Your doctor will discuss why they have prescribed you Fumaderm®, but it is usually because other treatments have not been helpful.

The leaflet, **Unlicensed medicines – a guide for patients**, has more information about unlicensed medicines. If you would like a copy, please ask your doctor, nurse or pharmacist. Alternatively you can call the pharmacy medicines helpline – contact details are at the end of this leaflet.

Is Fumaderm suitable for everyone?

You should not take Fumaderm® if:

- you have a severe stomach and/or intestinal disorders, such as a stomach ulcer or duodenal ulcer
- you have a severe liver or kidney disorder
- you are pregnant or breastfeeding
- you are allergic to any of the ingredients in Fumaderm®
- you are under 18 years old.

Women who become pregnant during treatment should stop taking Fumaderm® and tell the doctor prescribing the treatment immediately so that further advice can be

given. Please talk to your dermatology doctor for advice on taking Fumaderm® if you and your partner are trying to get pregnant.

How should I take Fumaderm® tablets?

The tablets should be taken by mouth (orally). They are enteric coated, which means they have a special coating that allows them to pass through the stomach and be absorbed in the small intestine. They should therefore be swallowed whole (not chewed) and taken with or after a meal.

Fumaderm® tablets come in two different strengths; **low strength** (white tablets called **Fumaderm® Initial**) and **high strength** (blue tablets called **Fumaderm® Full Strength**). The **Fumaderm® Initial** box contains 40 tablets and the **Fumaderm® Full Strength** box contains 70 tablets.

When you first start taking Fumaderm®, the dose will be gradually increased each week to allow your body to get used to the drug. The recommended dosing regimen is detailed below. This is flexible, depending on your individual response to the drug. Make sure you only take the dose that your dermatology doctor or specialist nurse has recommended for you.

Dosage (number of tablets)				
Week	Morning	Noon	Evening	FAE formulation
1	1	-	-	Fumaderm® Initial (white tablet)
2	1	-	1	
3	1	1	1	
4	1	-	-	Fumaderm® Full Strength (blue tablet)
5	1	-	1	
6	1	1	1	
7	2	1	1	
8	2	1	2	
9	2	2	2	

Make sure that you do not exceed the maximum dose of two tablets of **Fumaderm® Full Strength** three times a day. You may not need the maximum dose because your condition may be treated at a lower dose. Once your psoriasis has cleared, the dose will be gradually reduced to the lowest possible dose that keeps it clear.

How long will it take to work?

It may take four to six weeks before you see benefit with this treatment, so please continue to take it unless you are advised by your doctor to stop.

Are there any side effects associated with Fumaderm®?

Some side effects are very common in people taking Fumaderm®. These include stomach problems such as nausea (feeling sick), stomach discomfort, cramps, wind, feeling bloated and diarrhoea. These usually subside after a few days or weeks of continued treatment. Flushing and a sensation of heat in the skin occur in some people. Again, these usually become less intense with time.

Drinking enough water during the day (1.5 to 2 litres) may help to prevent side effects. If the side effects become intolerable, the dose may be lowered or the treatment stopped. Please discuss this with your dermatology doctor or specialist nurse first.

Longer term treatment with Fumaderm® can lower the level of white blood cells (part of the body's immune system). In most cases this occurs without any adverse effects. Sometimes, however, the level can become very low, persisting for a number of months or (very rarely) some years after stopping the treatment. We monitor your blood tests very carefully and we will discuss either reducing the dose or stopping treatment if we find that you have a very low white blood cell count. If the low count persists after stopping treatment, this may impact upon your future treatment options. Fumaderm® treatment may also cause liver or kidney problems, but this is rare and usually reversible once treatment is stopped.

It is important to have regular blood tests and attend your appointments while taking Fumaderm® so we can monitor you closely. The blood tests will be done every four weeks for three months and if normal, every two to three months thereafter. These are usually organised by the specialist team, although if you live a long distance from the hospital, we can work with your GP to arrange for local blood tests.

What should I do if I miss a dose?

Do not take extra tablets to make up for a missed dose. Just wait for your next scheduled dose and carry on as normal.

Can I take other medicines with Fumaderm®?

Some medicines interact with FAE, for example, those that affect the immune system or kidney function. It is therefore important that you tell your dermatology doctor, clinical nurse specialist or pharmacist if you start taking any new medicines, either on a regular or occasional basis. This includes medicines prescribed by your GP or other hospital doctors, medicines you have bought yourself over the counter, or alternative therapies such as herbal medicines.

Non-steroidal anti-inflammatory drugs (NSAIDs) are commonly-used medicines that can affect your kidneys. Examples include diclofenac, indomethacin, ibuprofen and naproxen. NSAIDs may also be found in some cold remedies. For pain relief, you can usually take paracetamol or codeine, but you should ask your dermatology doctor or pharmacist first. **Always check any new medicines prescribed for you with your doctor or pharmacist.**

Can I have vaccinations while I am taking Fumaderm®?

Some vaccines may be affected if you are taking Fumaderm®. It is essential you avoid **live vaccines** whilst taking Fumaderm® and for six months after treatment. This will be explained to you in more detail by your clinical nurse specialist.

Can I drink alcohol?

There are no known interactions between alcohol and Fumaderm®. We do however recommend that you keep your alcohol intake to a minimum as alcohol may itself worsen psoriasis.

How do I get further supplies of Fumaderm®?

Further supplies of Fumaderm® will be prescribed for you when you attend the specialist clinic and **can only be prescribed by your dermatologist**. Please check you have been prescribed a supply that will last you until your next appointment. If the hospital changes your appointment, please contact the clinic administrator or your nurse specialist to discuss access to further supplies of treatment (contact details are below).

Contact us

If you have any questions or concerns about taking Fumaderm®, please speak to your dermatology doctor, clinical nurse specialist, or pharmacist. Alternatively, please contact the Pharmacy Medicines Helpline on **020 7188 8748** (9am to 5pm, Monday to Friday).

The clinical nurse specialists can be reached on **020 7188 7847** (9am to 5pm, Monday to Friday)

For more information leaflets on conditions, procedures, treatments and services offered at our hospitals, please visit www.guysandstthomas.nhs.uk/leaflets

Pharmacy Medicines Helpline

If you have any questions or concerns about your medicines, please speak to the staff caring for you or call our helpline.

t: 020 7188 8748 9am to 5pm, Monday to Friday

Patient Advice and Liaison Service (PALS)

To make comments or raise concerns about the Trust's services, please contact PALS. Ask a member of staff to direct you to the PALS office or:

t: 020 7188 8801 at St Thomas' **t:** 020 7188 8803 at Guy's

e: pals@gstt.nhs.uk

Language Support Services

If you need an interpreter or information about your care in a different language or format, please get in touch using the following contact details.

t: 020 7188 8815 **fax:** 020 7188 5953

NHS 111

Offers medical help and advice from fully trained advisers supported by experienced nurses and paramedics. Available over the phone 24 hours a day.

t: 111

NHS Choices

Provides online information and guidance on all aspects of health and healthcare, to help you make choices about your health.

w: www.nhs.uk

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