FUMARIC ACID ESTERS

What are the aims of this leaflet?

This leaflet has been written to help you understand more about fumaric acid esters (FAE). It tells you what they are, how they work, how they are used to treat skin conditions, and where you can find out more about this drug.

What are fumaric acid esters?

The fumaric acid esters (FAE) are a medicine used to treat psoriasis, and have been used to treat psoriasis for over 30 years. The FAE are a popular licensed oral treatment for psoriasis in some countries; however, they are not yet licensed for treating psoriasis in the UK. You may, however, be prescribed them by your dermatologist.

What does “unlicensed” mean in relation to a drug?

An unlicensed drug is one that has not been awarded a Market Authorisation from the UK Medicines Healthcare Products Regulatory Agency (MHRA). Drug licenses are awarded following a rigorous process of evaluation by the MHRA following an application by a pharmaceutical company. Once awarded, the licensed drug can then be marketed and sold in the UK. In the absence of a license, the drug may still be prescribed in the UK, provided there is funding available locally to pay for it. Additionally, there must be a clear body of evidence to confirm that the drug is effective for the condition in question and that safety concerns have been adequately addressed. Even after such evidence has been supplied it is still a matter for the local formulary group (a multidisciplinary group who make decisions on the prescribing of medicinal drugs at a local level) to make a final decision on a case-by-case basis.

How do fumaric acid esters work?

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; this balance is disturbed in psoriasis. FAE change the immune system to reduce the imbalance of the cytokines.

**Which skin conditions are treated with fumaric acid esters?**

FAE are mainly used to treat moderate to severe psoriasis.

**Will fumaric acid esters cure my psoriasis?**

No, but there is usually a gradual improvement of psoriasis, which may clear up completely while FAE are being taken. If they are stopped, the psoriasis can be expected to return.

**How long will I need to take fumaric acid esters before they have an effect?**

FAE do not work immediately; it may be at least 4 to 6 weeks before you notice any benefit.

**When should I take fumaric acid esters?**

FAE are taken up to three times daily with or after food.

**What dose should I take?**

FAE are taken in gradually increasing doses. During the first week of treatment you will likely receive one tablet daily of the low-strength preparation “Fumaderm® Initial”. The second week of treatment involves “Fumaderm® Initial” one tablet twice daily. The third week involves “Fumaderm® Initial” one tablet three times daily. After this, you will commence the “Fumaderm® Full Strength” tablets, beginning with one tablet daily for the first week, then weekly increases in the dose to a maximum of six tablets daily of “Fumaderm® Full strength”. This dose may need to be maintained for a few weeks until your psoriasis clears completely. The dose of FAE will then be gradually reduced to the lowest dose that keeps your psoriasis clear, or nearly clear.

**What are the possible side effects of fumaric acid esters?**

In many patients, FAE can cause flushing (reddenning of the face and feeling hot) and headaches. This is most likely at the start of treatment and usually becomes less frequent over time.
Other side effects include a feeling of sickness, mild stomach upsets, stomach cramps, flatulence and diarrhoea.

**Are there any other side effects if fumaric acid esters are taken for a long time?**

FAE alter the body’s defence system and can lower the level of white blood cells in the body. They can also cause liver and kidney problems; however, these effects are rare and reversible when the treatment is stopped.

**How will I be monitored for the side effects of fumaric acid esters?**

You will need to have regular blood tests to check the blood cells as well as your kidney and liver function.

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**The BAD Biologic Interventions Register (BADBIR)**

If you have been prescribed fumaric acid esters for treatment of your psoriasis, you may be asked to take part in the national biologics register. This register is to compare the safety of different treatments for psoriasis and to see how well they work. It was set up to monitor some new treatments for psoriasis called biological treatments. The register will give doctors information on how best to use the treatments available for moderate to severe psoriasis. No information will be passed to the register without your informed consent.

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**Do the fumaric acid esters affect fertility or pregnancy?**

FAE do not affect fertility. Pregnancy should be avoided, so contraception is advised for women taking FAE. If you are planning a family, or if you become pregnant whilst taking FAE, you should contact your doctor as soon as possible. You should not breast feed if you are taking FAE. For men taking FAE (if the treatment is considered essential), it may be possible to continue them while trying to have a family, but this should always be discussed first with your dermatologist.

**Can I drink alcohol while I am taking fumaric acid esters?**

Yes. Alcohol itself, though, tends to worsen psoriasis so for this reason it is best kept to an absolute minimum.
Can I take other medicines at the same time as fumaric acid esters?

Some drugs interact with FAE and care should be taken. These include psoralens, medicines that affect the immune system including ciclosporin, retinoids, and medicines which affect kidney function. You should always tell your doctor and pharmacist that you are taking fumaric acid esters. FAE may cause problems with some drugs purchased over the counter and some herbal remedies so always check these with a pharmacist. However, there are many drugs which can be taken safely with FAE.

Where can I find out more about fumaric acid esters?

If you would like any further information about FAE, or if you have any concerns about your treatment, you should discuss this with your doctor or pharmacist. This information sheet does not list all the side effects this drug can cause. For full details, please see the drug information leaflet that comes with your medicine. Your doctor will assess your medical circumstances and draw your attention to side effects that may be relevant in your particular case.

Web links to detailed leaflets:

www.dermnetnz.org/treatments/fumaric-acid-esters.html

For details of source materials used please contact the Clinical Standards Unit (clinicalstandards@bad.org.uk).

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: its contents, however, may occasionally differ from the advice given to you by your doctor.

This leaflet has been assessed for readability by the British Association of Dermatologists’ Patient Information Lay Review Panel

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