



FUMARIC ACID ESTERS

What are the aims of this leaflet?

This leaflet has been written to help you understand more about fumaric acid esters (FAEs). 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?

Fumaric acid esters (FAEs) are chemical compounds that have been used as a treatment of psoriasis for over 30 years. The licensed FAE for treatment of moderate to severe plaque psoriasis in the UK is Skilarence® which contains dimethylfumarate (DMF), the active ingredient.

Which conditions are treated with Fumaric Acid Esters?

FAEs are used to treat adults with moderate to severe psoriasis and also have been reported in treating some patients with systemic lupus and severe disseminated granuloma annulare.

How do Fumaric Acid Esters work?

FAEs act on cells of the immune system. Their effects include normalising the balance of chemicals called cytokines which are upset in psoriasis.

Why have I been offered treatment with Fumaric Acid Esters?

FAEs may be offered to adult patients with moderate to severe psoriasis if other drug treatments do not work, are not tolerated or if they are considered unsuitable because of health problems.

Do Fumaric Acid Esters cure psoriasis?

No, psoriasis is a chronic skin disease and there is no known cure. Taking FAEs will aim to improve psoriasis and may sometimes clear the skin, but the psoriasis may return when the medication is stopped.

How long will I need to take Fumaric Acid Esters before it has an effect?

FAEs work over several weeks and it may take several months before the psoriasis really improves depending on the dose of medication. If there has not been a considerable improvement after 6 months, the medication should be stopped.

How do I take Fumaric Acid Esters?

FAEs are taken by mouth as tablets.

If your doctor has prescribed Skilarence®, the dosage is increased gradually as shown in the table below. Side effects can limit the increase of the dosage. Once psoriasis improves, the dosage may be reduced without losing effectiveness.

Week	Number of tablets			Total daily dose (mg)
	Morning	Midday	Evening	
Skilarence® 30 mg tablets				
1	0	0	1	30
2	1	0	1	60
3	1	1	1	90
Skilarence® 120 mg tablets				
4	0	0	1	120
5	1	0	1	240
6	1	1	1	360
7	1	1	2	480
8	2	1	2	600
9 onwards	2	2	2	720

What are the possible side effects of Fumaric Acid Esters?

All medicines can cause side effects. Detailed information about side effects is found in the package insert leaflet. Please read this carefully before starting treatment.

Most side effects from FAE are well tolerated, but as this medication affects the immune system there is a small chance of serious side effects.

Common side effects include:

- **Nausea, stomach cramps, flatulence and diarrhoea (up to 60%)**
- **Flushing, feeling hot, skin redness and irritation**
- **Headaches**

These side effects are more common at the start of treatment and usually become less frequent over time.

Rare side effects include:

- **Liver inflammation**
- **Kidney abnormalities** with loss of protein in the urine
- **Progressive Multifocal Leukoencephalopathy (PML) is a viral infection of the central nervous system but** reports of PML are extremely rare. The risk may increase in people taking FAEs who had/have persistently low levels of lymphocyte white blood cells, so it is very important that the blood count is checked regularly.

How will I be monitored for the side effects of Fumaric Acid Esters?

Before treatment is started, routine blood tests are carried out to check the full blood count, kidney function and liver function. Additional test may include HIV and hepatitis virus infection in people who are at risk of these infections. A urine sample is also dip-tested for sugar and protein. Blood tests and urine are checked regularly usually every 3 months. However, your doctor may recommend more frequent blood tests if necessary.

It is important to advise your doctor or nurse about any new symptoms or problems with your general health during FAE treatment as these may need further investigation.

In cases of severe or prolonged diarrhoea during treatment with FAEs, absorption of other medicinal products may be affected. Please contact your doctor for further advice.

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.

Do Fumaric Acid Esters affect fertility or pregnancy?

There are no human or animal data on the effects of FAEs on fertility. Pregnancy should be avoided during FAEs treatment as there is a possibility of harm to an unborn baby. FAEs should not be taken during breast feeding.

The efficacy of oral contraceptives may be reduced whilst on FAEs and the use of an alternative barrier contraceptive method is recommended to prevent possible failure of contraception.

Can I drink alcohol if I take Fumaric Acid Esters?

Yes, as there is no known interaction between alcohol and FAEs. However, strong alcoholic drinks increase the risk of stomach irritation with FAEs and should be avoided. Aim to keep your drinking within the recommended limits.

Can I take other medicines if I take Fumaric Acid Esters?

Most medicines are safe to take with FAEs, but they are usually avoided in people who are taking immune suppressing drugs such as Ciclosporin and are not usually given in combination with other psoriasis treatments such as phototherapy (UV therapy), retinoids or Methotrexate. Drugs which can cause kidney injury (nephrotoxic) should be avoided with FAEs.

Tell your doctor, nurse and pharmacist if you take any new medication, including over-the-counter treatment, herbal medicine and supplements.

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, nurse 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 records 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: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.

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

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