

# DIMETHYL FUMARATE (FUMARIC ACID ESTERS)



## WHAT ARE THE AIMS OF THIS LEAFLET?

This leaflet has been written to explain 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 information about this drug.

## WHAT ARE FUMARIC ACID ESTERS?

FAEs are chemical compounds that have been used to treat **psoriasis** for over 30 years. The FAEs which are licensed for treating moderate-to-severe plaque **psoriasis** in the UK are called Skilarence® which contains dimethyl fumarate (DMF), the active ingredient.

## HOW DO FUMARIC ACID ESTERS WORK?

FAEs act on the cells of the immune system. Their effects include normalising the balance of chemicals called cytokines which can be raised in **psoriasis**.

## WHY HAVE I BEEN OFFERED TREATMENT WITH FUMARIC ACID ESTERS?

FAEs may be offered to adult patients affected by 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 aims to improve **psoriasis**, control the inflammation, and may lead to skin clearance in a number of patients, but

**psoriasis** may return when the medication is stopped.

## HOW DO I TAKE FUMARIC ACID ESTERS?

FAEs are taken by mouth as tablets.

The following table shows the gradual increase of the dose FAEs. Side effects could slow or limit the increase in dosage. Once **psoriasis** improves, the dosage may be reduced while still being effective.

Number of tablets				
Week	Morning	Midday	Evening	Total daily dose (mg)
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

## HOW LONG WILL I NEED TO TAKE FUMARIC ACID ESTERS BEFORE IT HAS AN EFFECT?

The full dose of FAEs is introduced slowly and will increase over several weeks to achieve the maximum dose. It will therefore take some time before the

psoriasis really improves. If there has not been a considerable improvement after 6 months, the medication should be stopped. This will be discussed with you.

### **WHAT ARE THE POSSIBLE SIDE EFFECTS OF FUMARIC ACID ESTERS?**

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

Most side effects from FAEs are well tolerated, but as this medication affects the immune system there is a small chance of more 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 tests may include HIV and hepatitis virus infection. A urine sample is also 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 FAEs treatment as these may need further investigation or require discontinuation of the medication.

In cases of severe or prolonged diarrhoea during FAEs treatment, 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 the treatment of 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. However, 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 effectiveness of oral contraceptives may be reduced whilst taking FAEs. The use of an alternative barrier contraceptive method is recommended to prevent possible failure of contraception. Please discuss this with your doctor.

## CAN I DRINK ALCOHOL IF I TAKE FUMARIC ACID ESTERS?

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

## 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 suppressive 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 whilst taking FAEs.

Tell your doctor, nurse or 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 FAEs 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](http://www.dermnetnz.org/treatments/fumaric-acid-esters.html)

For details of source materials used please contact the Clinical Standards Unit ([clinicalstandards@bad.org.uk](mailto: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.

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

**BRITISH ASSOCIATION OF DERMATOLOGISTS**

PATIENT INFORMATION LEAFLET

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