PATIENT INFORMATION LEAFLET

APREMILAST

WHAT ARE THE AIMS OF THIS LEAFLET?

This leaflet has been written to help you understand more about apremilast. It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

WHAT IS APREMILAST AND HOW DOES IT WORK?

Apremilast is a medicine taken by the mouth which works by blocking an enzyme called PDE4.

PDE4 controls inflammation, which is when the skin gets red, swollen, and itchy.

Apremilast stops the way this enzyme works and reduces the inflammation in the skin. By doing so, apremilast can help improve the symptoms of psoriasis.

WHAT SKIN CONDITIONS ARE TREATED WITH APREMILAST?

Apremilast is used to treat moderate to severe psoriasis.

Psoriatic arthritis is a type of arthritis that can be linked with psoriasis and can also be treated with apremilast.

Apremilast may also be used in the treatment of Behçets.

WHY HAVE I BEEN SELECTED FOR TREATMENT WITH APREMILAST?

Apremilast can be prescribed when other medications have been tried and have not worked. These medications include ciclosporin, methotrexate and PUVA (psoralen and ultraviolet-A light) and others.

In some cases, apremilast is an option when these treatments are not suitable, or if they have caused unwanted side effects.

WILL APREMILAST CURE MY SKIN CONDITION?

No treatment currently can cure psoriasis, but apremilast can help manage the signs and symptoms of psoriasis.

HOW SHOULD I TAKE APREMILAST?

The tablet should be taken as prescribed by your doctor, normally every morning and every evening, approximately 12 hours apart. The tablet can be taken with or without food and should be swallowed whole.

WHAT DOSE SHOULD I TAKE?

The recommended dose is 30 mg twice daily. However, to reduce possible stomach and bowel symptoms (for example, nausea and diarrhoea) an initial lower dose will be given which will be increased gradually over the first week. These dosing instructions will be clearly labelled on a special starter pack, which will be provided when you first start taking apremilast.

HOW LONG WILL I NEED TO TAKE APREMILAST BEFORE I SEE AN EFFECT?

Reductions in skin itch, pain or discomfort are often seen within the first few weeks of treatment.

The greatest reduction in psoriasis severity (redness, thickness, and scale) is normally seen in the first 4 months of treatment. For example, in clinical trials, around 30 out of 100 patients had at least a 75% reduction in psoriasis severity by 4 months of treatment.

WHAT ARE THE COMMON SIDE EFFECTS OF APREMILAST?

Like all medications, apremilast may cause side effects. Headache, diarrhoea, and nausea are the most common side effects, more than 1 in 10 may be affected.

If experienced, these side effects mostly begin within the first 2 weeks of starting apremilast and usually resolve within 30 days, without any special treatment.

Other common side effects include respiratory tract infections, insomnia, fatigue, and muscle/joint pain.

WHAT ARE THE RARE SIDE EFFECTS OF APREMILAST?

Weight Loss

Weight loss of 5-10% of body weight was reported in 1 in 10 patients treated with apremilast in clinical studies. While this is uncommon, your weight may be monitored during your treatment with apremilast. If you lose weight unexpectedly, you may have to stop the treatment.

Depression

Clinical studies suggest up to 3 in 100 patients may develop depression while taking apremilast. Fewer than 1 in 1000 patients may develop suicidal thoughts or behaviour. The benefits and risks of apremilast should be discussed on a case-by-case basis before treatment is started. Always discuss your concerns with your doctor – let them know if you experience any change in mood or any suicidal thoughts.

You must inform your healthcare professional if you have any allergies or intolerances. Apremilast contains lactose. It may be unsuitable for you if you are lactose-intolerant.

HOW WILL I BE MONITORED FOR THE SIDE EFFECTS OF APREMILAST TREATMENT?

Your progress will be monitored by your healthcare professional. If you experience any side effects, you should discuss this with them. There is usually no need for regular blood tests while on apremilast, but your healthcare professional may choose to perform blood tests periodically.

CAN I HAVE IMMUNISATIONS (VACCINATIONS) WHILST ON APREMILAST?

While there is limited information about this at present, experts agree that live vaccines should not be given whilst taking apremilast.

DOES APREMILAST AFFECT FERTILITY, PREGNANCY OR BREASTFEEDING?

Apremilast has not been studied in pregnant woman or nursing mothers, so its effects on unborn babies and children remain unknown.

- It is recommended that apremilast is not taken if pregnant or planning to have a baby.
- It is also recommended that apremilast is not taken while breastfeeding.
- It is important that an effective method of contraception is used while taking apremilast.

MAY I DRINK ALCOHOL WHILE TAKING APREMILAST?

Apremilast does not interact with alcohol. However, as alcohol can worsen the symptoms of psoriasis, it is advised to avoid excessive intake of alcohol. The current recommended limits of alcohol intake should be followed: https://www.nhs.uk/live-well/alcohol-advice.

CAN I TAKE OTHER MEDICINES AT THE SAME TIME AS APREMILAST?

Most medications can be taken safely with apremilast. However, some may cause unwanted side effects. Because of this, it is important to inform your healthcare professional or pharmacist before taking any new prescriptions, over the counter medication and/or supplements including herbal medicines.

A group of medicines known as 'cytochrome P450 enzyme inducers' should not be taken with apremilast. This is because they can decrease the effect of apremilast. Cytochrome P450 enzyme inducers include medicines like rifampicin, phenobarbital, carbamazepine, phenytoin, and St John's wort.

WHERE CAN I GET MORE INFORMATION ABOUT APREMILAST?

This information leaflet does not list all the potential side effects of apremilast. To find out more about this medication please speak to your dermatologist, specialist nurse or pharmacist.

For more details, please read the drug information sheet, which comes as an insert with your prescription for apremilast.

It is important to report suspected side effects of medicines. The Medicines and Healthcare products Regulatory Agency (MHRA) manages the Yellow Card scheme. This scheme collects information and safety concerns about medicines and medical devices. Anyone can report these side effects or concerns by using:

- the Yellow Card website www.mhra.gov.uk/yellowcard or
- the Yellow Card app

Weblinks to other relevant sources:

www.dermnetnz.org/topics/apremilast

www.medicines.org.uk/emc/search?q=apremilast

Jargon Buster: www.skinhealthinfo.org.uk/support-resources/jargon-buster/

Please note that the British Association of Dermatologists (BAD) provides web links to additional resources to help people access a range of information about their treatment or skin condition. The views expressed in these external resources may not be shared by the BAD or its members. The BAD has no control of and does not endorse the content of external links.

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

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PRODUCED | NOVEMBER 2017
UPDATED | NOVEMBER 2024
NEXT REVIEW DATE | NOVEMBER 2027