

PATIENT INFORMATION ON

APREMILAST

(Brand names: Otezla®)

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **how you should take your medicine**
- **what are the possible side effects**
- **what tests you must have to monitor your condition and to detect unwanted effects**
- **other precautions you should take when you are taking apremilast.**

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking apremilast you must see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.
- If you are worried about any possible side effects you should contact your rheumatologist as soon as possible.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking apremilast.
- Do not breast feed or become pregnant while taking apremilast. If you are planning to become pregnant you should discuss this with your doctor.

For more information about PSORIATIC ARTHRITIS and other inflammatory conditions see Arthritis Australia's website: www.arthritisaustralia.com.au

What is apremilast?

Apremilast (brand name: Otezla®) is a medicine used to treat psoriatic arthritis, and moderate to severe plaque psoriasis. It is an immunosuppressive medicine, which means that it works by reducing the activity of the immune system.

In psoriatic arthritis this action helps to reduce inflammation and thus reduce pain and swelling in your joints.

What benefit can you expect from your treatment?

In psoriatic arthritis, treatment with apremilast can improve your general physical function by reducing the swelling and pain in the inflamed joints.

Apremilast has also been shown to improve the quality of life in patients with psoriatic arthritis. This means that the impact of your condition on daily activities, relationships and other factors should be less than it was before.

How is apremilast taken?

Apremilast is taken by mouth in tablet form. There are three different strengths of apremilast tablets: 10mg, 20mg and 30mg.

Sometimes when you start apremilast tablets, you may feel sick, get indigestion or an upset stomach or diarrhoea. To reduce the risk of these side effects, your doctor will start you on a treatment 'Starter pack' which starts at a much lower dosage.

Your treatment will start at the lower dose and will gradually be increased (also called "titrated") over the first 6 days of treatment. The 'Starter pack' has a schedule of which tablets to take, morning and night, during these first 6 days.

After the titration period, the usual dose is 30mg twice daily: one 30mg tablet in the morning and one 30mg tablet in the evening. By the end of day 6 you will have reached this recommended dose.

How to take apremilast

The tablets should be swallowed whole, not chewed or broken, with water. They can be taken with or without food.

Do not crush, split or chew the tablets.

Apremilast may be used with other arthritis medicines including:

- other Disease Modifying Anti-Rheumatic Drugs (DMARDs) such as methotrexate;
- steroid medicines such as prednisolone or cortisone injections into the joint;
- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen, Nurofen);
- simple pain medicines such as paracetamol.

There are separate information sheets for the medicines mentioned above.

When to take apremilast

Take your apremilast at the same time each day, one tablet in the morning and one in the evening.

If you have severe kidney problems your doctor may tell you to only take apremilast once a day, in the morning.

How long to take apremilast

Your doctor will tell you how long to continue taking your apremilast tablets. Do not stop taking your treatment unless advised by your doctor or unless side effects develop.

If you forget to take it

Take it as soon as you remember. If it is close to the time for the next dose, just skip the missed dose. Take the next dose at the regular time. Do not take a double dose to make up for the dose that you missed. If you are not sure what to do, ask your doctor or pharmacist.

Are there any side effects?

You might experience side effects with your treatment. Tell your doctor if you are concerned about possible side effects.

Most common possible side effects

- The most common side effects that may occur when taking apremilast are those affecting the stomach and bowel. These effects can include *excessive wind*, *bowel discomfort*, *loss of appetite*, *nausea* (feeling sick) and *diarrhoea*. These side effects often lessen after a few weeks of treatment. Starting apremilast with a lower dose in the 'Starter pack' helps to reduce the chance of these side effects.
- Other common side effects with apremilast include weight loss, skin rash, tiredness or difficulty sleeping, cough, cold or runny nose, headaches, increased blood pressure and back pain. These side effects, if they occur, often lessen with continued treatment.
- Depression, mood changes and suicidal behavior may occur and this should be discussed with your doctor if you experience such changes in mood.

Less common or rare possible side effects

- Allergic reactions may occur with apremilast. Seek medical attention immediately if you become short of breath, suffer wheezing or have difficulty breathing, or if you have swelling of the face, lips, tongue or other parts of the body.

Tell your doctor or pharmacist immediately if any of side effects you experience get worse, or if

you notice any side effects not listed in this leaflet.

to change the dose of these medicines while you take apremilast.

Use with other medicines

- Apremilast can interact with other medicines. You should tell your doctor (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines. You should also mention your treatment when you see other health professionals.
- In particular, apremilast can interfere with:
 - rifampicin, an antibiotic for tuberculosis and certain other antibiotics such as erythromycin or clarithromycin
 - some medicines used to treat seizures or epilepsy, such as carbamazepine, phenytoin and phenobarbitone
 - St John's Wort, a herbal medicine for mild anxiety and depression.

These medicines can affect apremilast or may affect how well it works. You may need

Use in pregnancy & breastfeeding

- Apremilast should not be taken during pregnancy or when breastfeeding.
- If you are a woman of child bearing age you should use effective contraception while taking apremilast.
- If you are planning to become pregnant, discuss this with your doctor.

How to store apremilast

- Store apremilast in a cool, dry place, away from direct heat and light (e.g. not in the bathroom).
- Keep all medicines out of reach of children.

Disposal

- If your doctor tells you to stop taking your medicine, or if the expiry date has passed, return any unused apremilast tablets to your pharmacy.
- Do not dispose of apremilast tablets via wastewater or household waste

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

If you are taking apremilast you should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.

The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicines mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medicine. It can be reproduced in its entirety but cannot be altered without permission from the ARA. The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.