

PATIENT INFORMATION ON LEFLUNOMIDE

(Brand names: Arabloc, Arava, Lunava)

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 leflunomide.**

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking leflunomide 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.
- It is important to have regular blood tests as directed by your doctor.
- If you are taking leflunomide and plan to become pregnant you must discuss the timing with your doctor.

For more information about RHEUMATOID ARTHRITIS and other inflammatory conditions see the Arthritis Australia website www.arthritisaustralia.com.au

What is leflunomide?

Leflunomide (brand names Arabloc, Arava) is a medicine used to treat rheumatoid arthritis and psoriatic arthritis.

It is an immunosuppressive medicine, which means that it works by reducing the activity of the immune system.

In rheumatoid and psoriatic arthritis this action helps to reduce inflammation and thus reduces pain and swelling in the joints. It also limits damage to the joints and helps to prevent disability in the long term.

Because leflunomide acts to reduce the damage to the joints, rather than just relieve the pain, it belongs to the group of medicines called **disease modifying antirheumatic drugs (DMARDs)**.

What benefit can you expect from your treatment?

Over 70% of people treated with leflunomide experience improvement of their rheumatoid arthritis. Some achieve remission, where the arthritis virtually disappears. As with many medicines used to treat rheumatoid arthritis, some people experience no benefit from leflunomide treatment.

Leflunomide does not work straight away. It usually takes 4 to 8 weeks for symptoms to start to improve. The full effect may take up to 26 weeks.

Other medicines may be given to improve your symptoms while waiting for the leflunomide to work.

How is leflunomide taken?

Leflunomide is taken by mouth in tablet form. There are three different strengths of

leflunomide tablets: 10mg, 20mg and 100mg. The usual dose is 10mg or 20mg once daily. Sometimes a higher dose may be given to begin with, but side effects are more common with this approach.

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

Leflunomide may be used with other arthritis medicines including:

- other DMARDs such as methotrexate
- biological DMARDs (a newer type of DMARD, which act on natural substances in the body that contribute to inflammation and joint damage)
- 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.

How long is the treatment continued?

Treatment with leflunomide can be continued for more than 10 years as long as it is effective and no serious side effects occur.

If leflunomide treatment is stopped for more than a few weeks there is a risk that your condition will worsen. Continue with your treatment unless advised by your doctor or unless side effects develop.

Are there any side effects?

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

If you do experience side effects, a reduction in dose may minimise these so that you can continue to take the medicine. Your doctor will advise on any dose changes that are necessary.

Most common possible side effects

- Leflunomide may cause a dry mouth or mouth ulcers

- Up to 20% of people experience stomach and bowel side effects when taking leflunomide. These effects can include *excessive wind, bowel discomfort, loss of appetite, nausea* (feeling sick) and *diarrhoea*. They often lessen after a few weeks of treatment; they may be reduced by drinking plenty of water.
- Up to 10% of people may have other common side effects such as *skin rash, reversible thinning of hair, increase in blood pressure* or *dizziness*. These side effects are not usually serious and may lessen with continued treatment.

Less common or rare possible side effects

There are some rare but potentially serious side effects with leflunomide. These are more likely if leflunomide is being taken with methotrexate.

- *Blood counts:* Leflunomide can cause a drop in the number of white blood cells, which are needed to fight infection. It can also cause a drop in the number of platelets, which help to stop bleeding.

Regular blood tests aim to pick these problems up early when they occur. However, if you develop a sore mouth, mouth ulcers, easy bruising, nosebleeds, bleeding gums, breathlessness, infection or fever tell your doctor straight away.

- *Infections:* There is an increased risk of developing some infections, especially herpes zoster (chicken pox and shingles). You should try to avoid contact with people who have these infections. If you have an infection or persistent fever, tell your doctor straight away.
- *Liver tests:* Leflunomide can cause liver tests to rise. These changes are usually mild and improve when the medicine is stopped or reduced.

The effects on the liver do not usually cause symptoms unless they are severe so regular blood tests are important. If you develop symptoms such as yellow discolouration of the whites of your eyes or yellow skin, tell your doctor straight away.

- There have been rare reports of *numbness (neuropathy)* in patients taking leflunomide.
- There have been rare reports of *lung inflammation* in patients taking leflunomide.

What precautions are necessary?

Blood tests

- As leflunomide may affect liver and blood cells, you **must** have regular blood tests during your treatment. This is very important as you may not get symptoms with some of these problems.
- Blood tests are particularly important during the first few months of treatment and when leflunomide is taken with methotrexate.
- As well as monitoring for side effects, blood tests help to monitor your condition to determine if the treatment is effective.
- You will need to have full blood counts and liver function tests every 2 to 4 weeks for the first few months of treatment and then every 1 to 3 months after that.
- Your general practitioner (GP) will be informed about the monitoring schedule. It is important to see your GP if you have been asked to do so as they have an important role to play in monitoring your condition.

Use with other medicines

- Leflunomide 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, leflunomide can interfere with phenytoin (for epilepsy), warfarin (a blood thinning medicine) and tolbutamide (for diabetes).
- If you are taking leflunomide, it is recommended you should not be immunised with 'live' vaccines such as

MMR (measles, mumps and rubella), BCG (Bacillus Calmette Guerin), OPV (oral polio vaccine) , Zostavax (Herpes Zoster) or yellow fever. Talk with your rheumatologist before receiving any vaccines.

Use with alcohol

- Because leflunomide can affect your liver, you should avoid heavy alcohol use while taking it.
- It is not known precisely what level of drinking is safe when on leflunomide. However, there is general agreement that 1 to 2 standard drinks taken once or twice a week is unlikely to cause a problem.
- Drinking more than 4 standard drinks on one occasion, even if infrequently, is strongly discouraged.

Surgery

- Your surgeon will discuss with you if you should stop leflunomide before or after surgery.

Use in pregnancy and breastfeeding

- Leflunomide 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 leflunomide.
- Because the medicine stays in the body for a long time, you should not conceive for 2 years after stopping treatment. If a couple wishes to conceive, in certain circumstances leflunomide can be 'washed out' from the body using other medication.
- It is not known if it is safe for men wanting to father a child to take leflunomide. Some experts advise leflunomide be ceased and 'washed out' in this circumstance.
- More detailed information is available at <https://rheumatology.org.au/gps/documents/RAPregnancyPrescribingGuidanceupdateApr19.pdf>

How to store leflunomide

- Store leflunomide 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.

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 leflunomide 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.