

Leflunomide APOTEX Tablets

Leflunomide

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about leflunomide. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

Leflunomide is used to treat rheumatoid arthritis and psoriatic arthritis.

It belongs to a group of medicines called disease-modifying anti-rheumatic drugs (DMARDs).

How it works

Leflunomide works by selectively interfering with the ability of white blood cells called lymphocytes to produce the disease response that ultimately leads to pain, inflammation and joint damage.

Leflunomide helps to slow down the process of joint damage and to relieve the symptoms of the disease, such as joint tenderness and swelling, pain and morning stiffness.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children under 18 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- leflunomide or teriflunomide
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have or have had any of the following medical conditions:

- any illnesses which reduce your body's natural defences, such as bacterial or viral infections
- an illness which severely lowers your body's resistance to disease, such as AIDS
- significant disease of the blood or bone marrow, such as anaemia
- serious allergic skin conditions, such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme
- liver disease
- hypoproteinaemia (when you do not have enough protein in your blood).

Do not take this medicine if you are pregnant or suspect you are pregnant, or you are planning to become pregnant.

Leflunomide may affect your developing baby if you take it during pregnancy or conception. It may increase the risk of birth defects.

If you want to become pregnant, you will need to stop taking leflunomide and may need to take another medicine to remove any leflunomide left in your body.

If there is any delay in the onset of menses or you suspect you are pregnant, notify your doctor immediately to test for pregnancy.

Do not take this medicine if you are not using reliable contraception.

Women of childbearing potential and men must use reliable contraception while taking leflunomide and for a certain period of time after you have stopped taking it.

Do not breastfeed if you are taking leflunomide.

Leflunomide may pass into human breast milk and there is a possibility that your baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- decrease in the number of white blood cells
- liver or kidney problems
- chronic (ongoing) infections
- an illness which lowers your body's resistance to disease
- peripheral neuropathy
- tuberculosis
- diabetes
- you are taking neurotoxic agents
- a history or have a family history of lung problems such as interstitial lung disease (an inflammation of lung tissue), a serious and potentially fatal disease.

Tell your doctor if you plan to father a child.

Leflunomide may increase the risk of birth defects. If you wish to father a child, you will need to stop taking

leflunomide and may need to take another medicine to get rid of any leflunomide left in your body.

Tell your doctor if you have recently been vaccinated or if you need to have a vaccination during treatment with this medicine or for 6 months after stopping leflunomide.

Live vaccines should be avoided while taking this medicine.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and leflunomide may interfere with each other. These include:

- teriflunomide, a medicine similar to leflunomide
- warfarin, used to prevent blood clots
- duloxetine, used to treat depression
- theophylline, used to treat respiratory conditions such as asthma
- furosemide, a diuretic
- zidovudine, an antiretroviral
- medicines used for diabetes (e.g. tolbutamide, repaglinide, pioglitazone or rosiglitazone)
- medicines used to treat epilepsy (e.g. phenytoin)
- antibiotics such as rifampicin, cefaclor, benzylpenicillin and ciprofloxacin
- medicines used in cancer treatment such as paclitaxel, topotecan, daunorubicin and doxorubicin
- some medicines used to treat cholesterol such as cholestyramine and statins (e.g.

rosuvastatin, simvastatin, atorvastatin or pravastatin)

- NSAIDs (non-steroidal anti-inflammatory drugs), such as indomethacin or ketoprofen
- methotrexate and sulfasalazine, used to treat autoimmune disorders such as rheumatoid arthritis
- some types of oral contraceptives
- medicines which have side effects on the blood.

These medicines may be affected by leflunomide or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking leflunomide.

Other medicines not listed above may also interact with leflunomide.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The usual dose for adults is 100 mg (five tablets of 20 mg or ten tablets of 10 mg) once a day for the first 3 days, then after that one 10 mg or 20 mg tablet daily.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include diarrhoea, stomach pain,

changes in your blood, or liver damage.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Tell your doctor if you are planning on stopping contraception, or if you are planning to father a child.

You must use a reliable contraceptive method (e.g. condoms or the oral contraceptive pill) whilst taking leflunomide. If you plan to stop your contraception, you must first discuss this with your doctor.

If you become pregnant whilst taking this medicine, stop taking your medicine and tell your doctor immediately.

This medicine may cause serious birth defects.

Tell your doctor immediately if you notice a fever or signs of an infection.

Leflunomide may lower your immunity.

Tell your doctor if you develop symptoms such as pins and needles or tingling in the hands or feet or numbness or weakness of the arms and legs.

Tell your doctor if you develop worsening or new symptoms such as breathing issues or a cough.

These may be symptoms of an inflammation of your lung tissue, which is potentially fatal.

Tell your doctor immediately and stop taking your medicine if you develop any symptoms of liver problems, including yellowing of

eyes, itchy and yellowing skin, bruising and bleeding easily.

Your doctor will check the health of your liver using blood tests on a regular basis while you are taking leflunomide.

Tell your doctors if you are going to have surgery or an anaesthetic or are going into hospital.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor will do blood tests and monitor your blood pressure before starting and during treatment. This is to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful while driving or operating machinery until you know how leflunomide affects you.

This medicine may cause tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

Leflunomide may worsen the effects of alcohol. It is recommended that you minimise your alcohol intake while taking leflunomide.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking leflunomide.

Leflunomide helps most people with rheumatoid and psoriatic arthritis, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea, vomiting, abdominal pain
- diarrhoea
- rashes, itchy skin
- hair loss
- loss of weight
- feeling unusually weak or tired

The above list includes the more common side effects of leflunomide.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- symptoms of an allergic reaction, such as swelling of the face, lips, mouth or throat; shortness of breath, wheezing or difficulty breathing; rash, itching, hives on the skin; fainting
- signs and symptoms of severe infection, such as fever
- severe upper stomach pain, often with nausea and vomiting
- severe skin rash or sores and blisters (sometimes in your mouth), often with flu-like symptoms
- pale skin, tiredness, increased infections or bruising

- new or worsening symptoms such as cough or trouble breathing, with or without a fever
- yellowing of the skin and eyes (jaundice)
- blisters and bleeding in the lips, eyes, mouth, nose and genitals
- thickened patches of red skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Storage and Presentation

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your

pharmacist what to do with any medicine left over.

Product description

What it looks like

Leflunomide APOTEX 10 mg tablets (bottle pack of 30 tablets):

White, round biconvex tablet. AUST R 251992.

Leflunomide APOTEX 20 mg tablets (bottle pack of 30 tablets):

Yellow, round biconvex tablets with a scoreline on one side. AUST R 251993.

* Not all strengths may be available.

Ingredients

Each tablet contains 10 mg or 20 mg of leflunomide, as the active ingredient.

Each tablet also contains the following:

- microcrystalline cellulose
- lactose monohydrate
- maize starch
- povidone
- crospovidone
- colloidal anhydrous silica
- magnesium stearate
- Opadry II complete film coating system OY-LS-28908 White (10 mg only)
- Opadry Aqueous Film Coating OY-SR-6497 Yellow (20 mg only).

This medicine is free from gluten, sucrose, tartrazine and other azo dyes.

Sponsor

This medicine is sponsored in Australia by:

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