

Leflunomide APOTEX Tablets

Contains the active ingredient leflunomide

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Leflunomide APOTEX Tablets. It contains the active ingredient leflunomide.

It is used to treat:

- rheumatoid arthritis
- psoriatic arthritis.

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.

How it works

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

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.

There is no evidence that this medicine is addictive.

Use in children

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 or have had any of the following:**
 - have any diseases which reduce your

body's natural defences such as bacterial or viral infections

- an illness which severely lowers your body's resistance to disease (e.g. AIDS)
- significant disease of the blood or bone marrow

- Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme (serious skin disorders with symptoms such as rashes, blisters, and/or peeling of large amounts of skin
- liver disease

- a condition called hypoproteinaemia (when you do not have enough protein in your blood).

- **You are pregnant or planning to become pregnant.**

Leflunomide may affect your developing baby if you take it during pregnancy.

- **You are not using reliable contraception.** Women of childbearing potential must use reliable contraception while taking leflunomide and for a certain period of time after stopping taking it.

- **You are breast-feeding or planning to breast-feed.**

Leflunomide may pass into human breast milk.

- **You are hypersensitive to, or have had an allergic reaction to, leflunomide or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; skin rash, itching or hives on the skin; fainting and/or hay fever-like symptoms. If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - decrease in the number of white blood cells
 - liver problems
 - kidney problems
 - chronic (ongoing) infections
 - an illness which lowers your body's resistance to disease
 - tuberculosis
 - diabetes
 - you are taking neurotoxic agents.
3. You have, have had in the past, or have a family history of, lung problems such as interstitial lung disease (an inflammation of

lung tissue), which is a serious and potentially fatal disease.

4. You are currently pregnant or you plan to become pregnant or plan to father a child. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

Leflunomide may increase the risk of birth defects. If you wish to become pregnant or 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.

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

5. You are currently breast-feeding or you plan to breast-feed. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.

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

6. You plan to father a child.
7. You plan to stop using contraception.
8. You have recently been vaccinated or plan to get a vaccination.
9. You are planning to have surgery or an anaesthetic.
10. You are currently receiving or are planning to receive dental treatment.
11. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Some medicines may interact with leflunomide. These include:

- warfarin, an anticoagulant medicine (i.e. a medicine used to stop blood from clotting)
- medicines used for diabetes e.g. tolbutamide
- medicines used to treat epilepsy e.g. phenytoin
- medicines used for tuberculosis (TB) e.g. rifampicin
- cholestyramine, a medicine used to reduce high levels of cholesterol in the blood. This medicine, along with activated charcoal, may also be used to decrease the amount of leflunomide in your body
- medicines which may affect the liver, such as certain NSAIDs (non-steroidal anti-inflammatory drugs) and methotrexate
- medicines which cause damage pertaining to blood.

In certain situations, for example, if you experience a serious side effect, you change your medication or you want to fall pregnant, your doctor will ask you to take medication that will help your body get rid of Leflunomide faster.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Your doctor can tell you if you are taking any of these medicines. They may also 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 carefully all directions given to you by your doctor.

Their instructions may be different to the information in this leaflet.

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.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

The usual dose is as follows:

100 mg (five tablets of 20 mg or ten tablets of 10 mg) once a day for the first 3 days, then 20 mg (one 20 mg tablet or two 10 mg tablets) once a day.

For some people, the daily dose may be reduced to 10 mg.

Follow the instructions your doctor give you.

These directions may differ from the information contained in this leaflet. If you take the wrong dose, Leflunomide may not work as well.

How to take it

Swallow the tablets whole, with a glass of water.

When to take it

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

It does not matter if you take it before, with or after food.

How long to take it

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

Whilst this medicine helps to control your condition it does not cure it. It is important to keep taking your medicine even if you feel well. Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

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 missed doses.

This may increase the chance of you experiencing side effects.

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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much leflunomide, you may experience diarrhoea, stomach pain, changes in your blood, or liver damage.

While you are taking this medicine

Things you must do

Your doctor will do a blood test & monitor your blood pressure before you start taking this medicine.

Make sure you visit your doctor for blood and liver function tests regularly, as advised by your doctor.

Tell your doctor that you are taking this medicine if:

- You are about to be started on any new medicine.
- You are planning on stopping contraception. While you are taking this medicine you must use a reliable contraceptive such as condoms or the oral contraceptive pill. If you are planning on stopping contraception, you must discuss this with your doctor before doing so.
- You are planning to father a child.
- You are pregnant or are planning to become pregnant. This medicine may cause serious birth defects. Tell your doctor immediately if you become pregnant and do not take any more of your medicine.
- You are breast-feeding or planning to breast-feed.
- You notice a fever or signs of an infection. You must inform your doctor immediately. Leflunomide may lower your immunity.
- You develop symptoms such as pins and needles or tingling in the hands or feet or numbness or weakness of the arms and legs.
- 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.
- You develop liver problems. Symptoms of liver problems include yellowing of eyes, itchy and yellowing skin, bruising and bleeding easily. If you notice any of these symptoms, do not take any more of your medicine and notify your doctor immediately. Your doctor will check your liver function using blood tests on a regular basis while you are taking leflunomide.
- You need to have a vaccination or immunisation while you are taking this medicine. This also applies for 6 months after you have stopped taking leflunomide. Live vaccines should be avoided while taking this medicine.

- You are about to have any blood tests.
- You are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up. Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

The effects of alcohol could be made worse while taking Leflunomide. It is recommended that you minimise your alcohol intake while taking Leflunomide.

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking this medicine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not. You may need medical treatment if you get some of the side effects.

Leflunomide works by decreasing your body's immune response. Because of this, you may develop side effects listed below.

Tell your doctor if you notice any of the following side effects:

- diarrhoea
- rashes, itchy skin
- hair loss
- loss of weight
- feeling unusually weak or tired.

These are the more common side effects of leflunomide.

Tell your doctor as soon as possible if you notice any of the following:

- signs and symptoms of severe infection e.g. fever
- severe upper stomach pain, often with nausea and vomiting
- severe skin rash or sores in your mouth
- your skin becomes pale, you start to feel tired, you become prone to infections or bruising
- if you develop new or worsening symptoms such as cough or trouble breathing, with or without a fever.

The above side effects are mostly uncommon. These may be serious side effects and you may need medical attention.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- hives
- fainting
- yellowing of the skin and eyes (jaundice).

The above side effects are very rare. These are very serious side effects and you may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to leflunomide, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

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

Do not store your 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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What Leflunomide APOTEX Tablet looks like

Leflunomide 10 mg tablet is a film coated, white, round, biconvex tablet.

Leflunomide 20 mg tablet is a film coated, yellow, round biconvex tablets with a scoreline on one side.

Leflunomide tablets are available in:

Bottle packs of 30 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

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

It also contains the following inactive ingredients:

- cellulose - microcrystalline
- lactose
- starch - maize
- povidone
- crospovidone
- silica - colloidal anhydrous
- magnesium stearate
- Opadry II complete film coating system OY-LS-28908 White (PI 4527) (10 mg only)
- Opadry Aqueous Film Coating OY-SR-6497 Yellow (PI 3965) (20 mg only).

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

Australian Registration Numbers

Leflunomide APOTEX 10 mg Tablets (bottle pack): AUST R 251992.

Leflunomide APOTEX 20 mg Tablets (bottle pack): AUST R 251993.

Sponsor

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