

Apo-Leflunomide

leflunomide

10mg and 20mg tablets

What is in this leaflet

Please read this leaflet carefully before you start using Apo-Leflunomide.

This leaflet answers some common questions about Apo-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 Apo-Leflunomide against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Apo-Leflunomide is used for

The name of your medicine is Apo-Leflunomide tablet. It contains the active ingredient leflunomide.

Apo-Leflunomide is a type of medicine used to treat:

- rheumatoid arthritis or
- psoriatic arthritis.

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.

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.

Your doctor may have prescribed Apo-Leflunomide for another reason.

Ask your doctor if you have any questions about why Apo-Leflunomide has been prescribed for you.

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

Before you use Apo-Leflunomide

When you must not use it

Do not use Apo-Leflunomide if you:

- have any diseases which reduce your body's natural defences such as bacterial or viral infections
- have any diseases of the blood
- have any serious skin disorders
- have liver disease
- have a condition called hypoproteinaemia (when you do not have enough protein in your blood)
- are pregnant or plan to become pregnant
- are not using reliable birth control
- are breastfeeding

You must not become pregnant while taking Leflunomide and for a certain period of time after stopping Leflunomide.

Leflunomide may increase the risk of birth defects.

Women of childbearing potential must use reliable contraception while taking Leflunomide.

Do not take it if you are breastfeeding or planning to breastfeed.

Leflunomide passes into breast milk and therefore there is a possibility that the breastfed baby may be affected.

Do not take Leflunomide if you are allergic to it, teriflunomide or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

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.

Do not give Leflunomide to a child or adolescent.

Leflunomide is not approved for use in children or adolescents under 18 years old.

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Apo-Leflunomide, talk to your doctor.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet.
- any other substances, such as foods, preservatives or dyes.

Tell your doctor immediately if you think you could be pregnant while taking Leflunomide.

Tell your doctor if you intend to become pregnant or father a child.

Leflunomide may increase the risk of birth defects. To reduce any risk to the developing baby, you will need to stop taking Leflunomide and may need to undergo a wash-out procedure. Your doctor will discuss the wash-out procedure with you.

Tell your doctor if you are breastfeeding or planning to breastfeed.

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

- a decrease in the number of white blood cells
- liver problems
- kidney problems
- chronic infections
- an illness which lowered your body's resistance to disease
- tuberculosis
- lung problems, such as interstitial lung disease (an inflammation of lung tissue) which is a serious and potentially fatal disease

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you start using Apo-Leflunomide.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Apo-Leflunomide.

Some medicines may interfere with Apo-Leflunomide. These include:

- warfarin, a medicine used to stop blood clots
- some medicines used for diabetes

- some medicines used to treat epilepsy
- some medicines used for tuberculosis (TB)
- some medicines used to lower cholesterol

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

Other medicines not listed above may also interact with leflunomide..

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.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Leflunomide.

How to use Apo-Leflunomide

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 standard dose for this medicine is one 100mg tablet per day for the first 3 days, and after that one 10mg or 20mg tablet daily.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

How to take it

Swallow the tablets whole with a full 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.

If you are not sure when to take it, ask your doctor or pharmacist.

How long to take it

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

The medicine helps control your condition, but it does not cure it. Therefore, you must take it every day.

Make sure you have enough to last over weekends and holidays.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

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 there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

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

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

While you are using Apo-Leflunomide

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Apo-Leflunomide.

If you are about to be started on any new medicine tell your doctor, dentist and pharmacist that you are taking Apo-Leflunomide.

If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.

Tell your doctor before stopping contraception. You must continue using appropriate reliable contraception (the 'Pill' or condoms) while you are taking Apo-Leflunomide.

If you have an infection or notice a fever or signs of an infection while taking this medicine, tell your doctor immediately.

If your skin becomes itchy or yellow, if the whites of your eyes become yellow, or if you start to bleed or bruise easily, stop taking it and tell your doctor or pharmacist immediately.

You may be developing a liver problem. Your doctor may need to take blood samples to monitor the health of your liver and blood cells while you are taking Apo-Leflunomide.

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

Inflammation of the lung tissue which can be fatal has been reported in some patients.

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 need to have a vaccination during treatment with this medicine or for 6 months after stopping treatment.

Things you must not do

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

Do not give Apo-Leflunomide to anyone else, even if they have the same condition as you.

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

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

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Leflunomide.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Leflunomide or if you have any questions or concerns.

It helps most people with 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 treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

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

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

- diarrhoea
- rashes, itchy skin
- hair loss
- weight loss
- unusual tiredness or weakness
- nausea and vomiting
- abdominal pain

These are the more common side effects of Leflunomide.

Tell your doctor as soon as possible, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- signs and symptoms of severe infection eg. 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.
- if you develop blisters and bleeding in the lips, eyes, mouth, nose and genitals.

These may be serious side effects of Leflunomide and you may need urgent medical attention. Serious side effects are uncommon.

Leflunomide decreases your body's immune response and can cause some of the side effects listed above.

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)
- thickened patches of red skin

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Leflunomide. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

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

After using Apo-Leflunomide

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 25°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.

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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

Product description

What it looks like

Apo-Leflunomide 10mg tablet: white, round, biconvex tablet, engraved "LE" over "10" on one side and "APO" on the other side.

Apo-Leflunomide 20mg tablet: white, arc triangular shaped biconvex tablet, engraved "LE" over "20" on one side and "APO" on the other side.

Apo-Leflunomide 10mg and 20mg tablets are available in bottle or blisters of 30 tablets.

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

Ingredients

Active ingredient:

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

Inactive ingredients:

- Colloidal silicon dioxide
- Crospovidone
- Lactose
- Magnesium stearate

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

This medicine contains lactose.

Sponsor Details

Apo-Leflunomide is supplied in New Zealand by:

Apotex NZ Ltd
32 Hillside Road
Glenfield
AUCKLAND 0627

Telephone: (09) 444 2073

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