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(For additional information [see "Leflunomide: Drug information"](#) and [see "Leflunomide: Pediatric drug information"](#))

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Brand Names: US

Arava

Brand Names: Canada

ACCEL-Leflunomide; APO-Leflunomide; Arava; PMS-Leflunomide; SANDOZ Leflunomide; TEVA-Leflunomide

Warning

- This drug may cause harm to the unborn baby or loss of the unborn baby if you take it while you are pregnant.
- Do not take if you are pregnant or if you may get pregnant and are not using birth control to prevent pregnancy. A pregnancy test will be done to show that you are NOT pregnant before starting this drug. Use birth control that you can trust to prevent pregnancy while taking this drug. Keep using this birth control until you go through a process to get rid of extra leflunomide in your body. You will need to have blood tests showing that your body is free of leflunomide before you stop taking birth control. If you get pregnant while taking this drug, call your doctor right away.
- Very bad and sometimes deadly liver problems have happened with this drug. Tell your doctor if you have liver disease. This drug must not be used in people with certain liver problems. Have your liver function checked as you were told by your doctor.

- Tell your doctor if you are taking any drugs that can raise the chance of liver problems. There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure.

What is this drug used for?

- It is used to treat rheumatoid arthritis.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to leflunomide or any other part of this drug.
- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have any of these health problems: Bone marrow disease or low blood cell counts.
- If you have an infection.
- If you have a weak immune system.
- If you are taking teriflunomide.
- If you are breast-feeding. Do not breast-feed while you take this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.

- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- High blood pressure has happened with this drug. Have your blood pressure checked as you have been told by your doctor.
- Talk with your doctor before getting any vaccines while you take this drug and after you stop taking it. Vaccine use with this drug may either raise the chance of an infection or make the vaccine not work as well. Talk with your doctor.
- You may have more of a chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu. Some infections have been very bad and even deadly.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- You will need a TB (tuberculosis) test before starting this drug.
- This drug will stay in your body for some time after you stop taking it. Sometimes, your doctor may give you other drugs to get rid of this drug faster. Talk with your doctor.
- This drug may add to the chance of getting some types of cancer. Talk with the doctor.
- Nerve problems have happened with this drug. Most of the time, these nerve problems went away after this drug was stopped. Sometimes, people had nerve problems that did not go away even after this drug was stopped. Talk with the doctor.
- A severe and sometimes deadly reaction has happened. Most of the time, this reaction has signs like fever, rash, or swollen glands with problems in body organs like the liver, kidney, blood, heart, muscles and joints, or lungs. If you have questions, talk with the doctor.
- If you are 60 or older, use this drug with care. You could have more side effects.
- If your sex partner may get pregnant or you wish to father a child, talk with your doctor.
- If you are a woman and you miss a period, have unprotected sex, or think that

your birth control has not worked, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- A burning, numbness, or tingling feeling that is not normal.
- Pale skin.
- Low blood cell counts have happened with this drug. If blood cell counts get very low, this can lead to bleeding problems, infections, or anemia. Call your doctor right away if you have signs of infection like fever, chills, or sore throat; any unexplained bruising or bleeding; or if you feel very tired or weak.
- A severe skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause severe health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.
- Some people have had lung problems with this drug. Sometimes, this has been deadly. Call your doctor right away if you have signs of lung problems like

shortness of breath or other trouble breathing, cough that is new or worse, or fever.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Upset stomach or throwing up.
- Stomach pain or diarrhea.
- Hair loss.
- Feeling dizzy, tired, or weak.
- Back pain.
- Headache.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take with or without food.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.

- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature.
- Protect from light.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine. The use of this information is governed by the Lexicomp End User License Agreement, available at <https://www.wolterskluwer.com/en/solutions/lexicomp/about/eula>.

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