PATIENT & CAREGIVER EDUCATION

Leflunomide

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Arava

Brand Names: Canada

ACCEL-Leflunomide; APO-Leflunomide; Arava [DSC]; MAR-Leflunomide; PRO-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 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.
- This drug may affect how wounds heal. If you need to

have surgery, you may need to stop this drug before surgery. Start taking it again after surgery as you have been told by your doctor. Call your doctor right away if you have a wound that does not heal or any other wound problems.

- Have your blood work and other lab tests checked as you have been told by your 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.
- This drug may lower the ability of the bone marrow to make blood cells that the body needs. If blood cell counts get very low, this can lead to bleeding problems, infections, or anemia. If you have questions, talk with the doctor.
- You may have more of a chance of getting an infection. Some infections have been severe or deadly. Wash hands often. Stay away from people with infections, colds, or flu.

- 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.
- Drugs that may suppress the immune system like this drug may raise the risk of cancer. If you have questions, 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.
- 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 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, tiredness, decreased appetite, 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.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of bleeding like throwing up or coughing up blood; vomit that looks like coffee grounds; blood in the urine; black, red, or tarry stools; bleeding from the gums;

abnormal vaginal bleeding; bruises without a cause or that get bigger; or bleeding you cannot stop.

- A burning, numbness, or tingling feeling that is not normal.
- Pale skin.
- Skin ulcers or sores.
- Severe skin reactions may happen with this drug. These include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and other serious reactions. Sometimes, body organs may also be affected. These reactions can be deadly. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin; red or irritated eyes; sores in your mouth, throat, nose, eyes, genitals, or any areas of skin; fever; chills; body aches; shortness of breath; or swollen glands.
- 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.

You may report side effects to the FDA at 1- 800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

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 protected 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.
- Some drugs may have another patient information leaflet. Check with your pharmacist. 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.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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