

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; 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 your child takes it during pregnancy.
- Do not let your child take this drug while pregnant, or if your child may get pregnant and is not using birth control. A pregnancy test will be done to show that your child is NOT pregnant before starting this drug. Have your child use birth control while taking this drug. After stopping this drug, your child must keep using birth control until a special process is done to remove extra leflunomide from the body. Blood tests will be done to show that the body is free of this drug. If your child gets pregnant while taking this drug, call the doctor right away.
- Severe and sometimes deadly liver problems have happened with this drug. Tell the doctor if your child has liver disease. This drug must not be used in people with certain liver problems. Have your child's liver function checked as you were told by the doctor.
- Tell the doctor if your child is taking any drugs that can raise the chance of liver problems. There are many drugs that can do this. Ask the doctor or pharmacist if you are not sure.

What is this drug used for?

- It is used to treat juvenile arthritis.
- This drug is not approved for use in children. However, the doctor may decide the benefits of taking this drug outweigh the risks. If your child has been given this drug, ask the doctor for information about the benefits and risks. Talk with the doctor if you have questions about giving this drug to your child.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has any of these health problems: Bone marrow disease or low blood cell counts.
- If your child has an infection.
- If your child has a weak immune system.
- If your child is taking teriflunomide.

If your child is breast-feeding a baby:

- Be sure your child does not breast-feed a baby while taking this drug.

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

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

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- This drug may affect how wounds heal. If your child has surgery, you may need to stop giving this drug before surgery. Start giving it again after surgery as you are told by the doctor. Call the doctor right away if your child has a wound that does not heal or any other wound problems.
- Have your child's blood work and other lab tests checked as you have been

told by the doctor.

- High blood pressure has happened with this drug. Have your child's blood pressure checked as you have been told by the doctor.
- Talk with the doctor before your child gets any vaccines while taking this drug and after your child stops 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 the 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.
- Your child may have more chance of getting an infection. Some infections have been deadly. Have your child wash hands often. Have your child stay away from people with infections, colds, or flu.
- Your child may bleed more easily. Make sure your child is careful and avoids injury. Be sure your child has a soft toothbrush.
- Your child will need a TB (tuberculosis) test before starting this drug.
- This drug will stay in your child's body for some time after your child stops taking it. Sometimes, the doctor may give your child other drugs to get rid of this drug faster. If you have questions, talk with the 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 your child is or may be sexually active:

- If your child misses a period, has unprotected sex, or thinks that their birth control has not worked, call the doctor right away.
- If your child's sex partner may get pregnant or your child wishes to father a child, talk with the doctor.

What are some side effects that I need to call my child's 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 child's doctor or get medical help right away if your child has 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 your child has signs like red, swollen, blistered, or peeling skin; red or irritated eyes; sores in the 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 child's doctor right away if your child has 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 child's doctor or get medical help if any of these side effects or any other side effects bother your child 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 child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

- Give this drug with or without food.
- Keep giving this drug to your child as you have been told by your child's doctor or other health care provider, even if your child feels well.

What do I do if my child misses a dose?

- Give a missed dose as soon as you think about it.
- If it is close to the time for your child's next dose, skip the missed dose and go back to your child's normal time.
- Do not give 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 child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child's 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 provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at <https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms>.

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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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