

Brightside Specialty Pharmacy

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Patient Education for LEFLUNOMIDE 20 MG TABLET

Must be compliant with therapy Call doctor if rash develops Physician must know patient's complete medical history Lab tests may be ordered to monitor therapy Report signs of liver trouble to doctor promptly (jaundice etc) Many drug-drug interactions possible with this drug May suppress immune system. Avoid infections/newly immunized people. Teratogenic-Avoid getting pregnant or use while pregnant or nursing.

Important to try not to skip doses Call your doctor if you get a rash Tell doctor your complete medical history Lab tests may be ordered to monitor therapy Call MD if new abdominal pain/yellowing eyes/skin Review all drugs you are taking with your doctor Avoid infections and recently immunized people Avoid getting pregnant or use when pregnant/nursing

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

LEFLUNOMIDE - ORAL

(leh-FLEW-no-mide)

COMMON BRAND NAME(S):

Arava

WARNING:

Leflunomide must not be used during pregnancy because

it may cause serious harm (possibly death) to an unborn baby. Women of childbearing age must have a negative pregnancy test before starting this medication. They must also use reliable forms of birth control before starting leflunomide, while taking it, and after stopping it until they have finished taking another drug that helps leflunomide leave the body and confirmed through 2 blood tests that the leflunomide levels are very low (see How to Use section). If you become pregnant or think you may be pregnant, inform your doctor right away (see Precautions section).

This drug may rarely cause serious (possibly fatal) liver disease. Most cases occur within 6 months of taking this drug. If you already have liver disease (such as hepatitis B or C), leflunomide should not be used. Liver function (blood) tests must be performed periodically while taking leflunomide. Tell your doctor right away if you notice nausea/vomiting that doesn't stop, dark urine, light-colored stools, stomach/abdominal pain, yellowing eyes/skin. See Drug Interactions section.

USES:

This medication is used to treat rheumatoid arthritis, a

condition in which the body's defense system (immune system)

fails to recognize the body as itself and attacks the healthy tissues around the joints. Leflunomide helps to reduce the joint damage/pain/swelling and helps you to move better. It works by weakening your immune system and decreasing swelling (inflammation).

OTHER USES:

This section contains uses of this drug that are not

listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

This drug may also be used for psoriatic arthritis. It may also be used to reduce the risk of rejection of organ transplant.

HOW TO USE:

Take this medication by mouth with or without food,

usually once daily or as directed by your doctor. Take this medication exactly as prescribed. You may be instructed to take a higher dose for the first 3 days of treatment.

Dosage is based on your medical condition and response to therapy.

Take this medication regularly in order to get the most benefit from it. To help you remember, take it at the same time each day.

After treatment is stopped, a different drug (cholestyramine) may be given as directed to help remove leflunomide from your body. This procedure is used if you need a rapid removal of the drug from your system (for example, if you are a female/male planning to have children, or suffering from severe side effects). Without the procedure, the drug may stay in your body for up to 2 years. Consult your doctor or pharmacist for more details.

Tell your doctor if your symptoms last or get worse.

SIDE EFFECTS:

Diarrhea, nausea, and dizziness may occur. If any

of these effects last or get worse, tell your doctor or pharmacist promptly.

Remember that this medication has been prescribed because your

doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: cough, numbness/tingling of hands/feet, hair loss, chest pain, fast/pounding heartbeat, increased thirst/urination, muscle cramp/pain, mental/mood changes, vision changes, easy bruising/bleeding, unusual growths/lumps, unexplained weight loss, unusual tiredness.

This medication may raise your blood pressure. Check your blood pressure regularly and tell your doctor if the results are high.

This medication may lower your ability to fight infections. This may make you more likely to get a serious (rarely fatal) infection or make any infection you have worse. Get medical help right away if you have any signs of infection (such as sore throat that doesn't go away, fever, swollen lymph nodes, chills).

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

Leflunomide can commonly cause a mild rash that is usually not serious. However, you may not be able to tell it apart from a rare rash that could be a sign of a severe allergic reaction. Get medical help right away if you develop any rash.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

Before taking leflunomide, tell your doctor or

pharmacist if you are allergic to it; or to teriflunomide; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: immune system disorder (such as HIV infection), current/recent infection (such as tuberculosis), cancer, bone marrow/blood disorder, kidney disease, liver disease (such as hepatitis B or C), alcohol abuse, heart disease (such as congestive heart failure), high blood pressure, lung disease.

This drug may make you dizzy. Alcohol or marijuana (cannabis) can make you more dizzy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis). Alcohol may also cause liver disease.

Do not have immunizations/vaccinations without the consent of your doctor, and avoid contact with people who have recently

received oral polio vaccine or flu vaccine inhaled through the nose.

Leflunomide can make you more likely to get infections or may worsen any current infections. Avoid contact with people who have infections that may spread to others (such as chickenpox, measles, flu). Consult your doctor if you have been exposed to an infection or for more details.

This medication must not be used during pregnancy. It may harm an unborn baby. Before starting this medication, women of childbearing age must have a negative pregnancy test before starting this medication. Men and women must use effective forms of birth control (such as condoms and birth control pills) while taking this medication. Consult your doctor for more details and to discuss reliable forms of birth control. (See also Warning section.)

It is not known whether this medication affects the sperm. To minimize any possible risk, the manufacturer recommends that men wishing to father a child should consider stopping the medication and using another drug (cholestyramine) as directed to help this drug leave the body before attempting to father a child. (See How to Use section.) Consult your doctor for more details.

This drug may pass into breast milk and could have undesirable effects on a nursing infant. Breast-feeding is not recommended while using this drug. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

See also How to Use Section.

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: warfarin, rifamycins (such as rifampin), drugs affecting the liver (such as methotrexate), cholestyramine, other drugs that weaken the immune system (such as tacrolimus, cyclosporine).

Because teriflunomide (used to treat multiple sclerosis) is very similar to this medication, do not take it while you are taking leflunomide.

OVERDOSE:

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center.

NOTES:

Do not share this medication with others.

A skin test to check for tuberculosis should be performed before you start this medication. While taking this medication, laboratory and/or medical tests (such as liver function, blood counts, blood pressure) should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, take it as soon as you

remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

MEDICAL ALERT:

Your condition can cause complications in a

medical emergency. For information about enrolling in MedicAlert, call 1-888-633-4298 (US) or 1-800-668-1507 (Canada).

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