PATIENT & CAREGIVER EDUCATION

Ledipasvir and Sofosbuvir

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

Harvoni

Brand Names: Canada

Harvoni

Warning

- You will be tested for hepatitis B before starting this drug. In people who have had hepatitis B or carry the virus, the virus has become active again during or after treatment with drugs like this one. This can lead to severe and sometimes deadly liver problems. People with hepatitis B and hepatitis C will be watched closely during and after treatment.

What is this drug used for?

- It is used to treat hepatitis C infection.

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 ever had liver problems other than hepatitis C.
- If you are taking another drug that has the same drug in it.
- If you take any drugs (prescription or OTC, natural products, vitamins) that must not be taken with this drug, like certain drugs that are used for HIV, infections, seizures, and others. There are many drugs that must not be taken with 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?

For all patients taking 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 be used with ribavirin. If you are also taking ribavirin, talk with the doctor about the risks and side effects that may happen.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- It is not known if this drug stops the spread of diseases like hepatitis that are passed through blood or having sex. Do not have any kind of sex without using a latex or polyurethane condom. Do not share needles or other things like toothbrushes or razors. Talk with your doctor.
- Severe slow heartbeat has happened when amiodarone was given with sofosbuvir and certain other hepatitis C drugs. Sometimes a pacemaker was needed. Rarely, this has been deadly. Slow heartbeat has happened up to 2 weeks after starting hepatitis C treatment. Tell your doctor if you are taking amiodarone or have recently stopped taking it. You will need to be watched closely. Call your doctor right away if you have signs of slow heartbeat like chest pain, confusion, dizziness, passing

out or almost passing out, memory problems, shortness of breath, tiredness, or weakness.

- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

Children:

- If giving this drug to your child and your child's weight changes, talk with the doctor. The dose of this drug may need to be changed.

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.

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:

- Feeling dizzy, tired, or weak.
- Headache.
- Upset stomach.
- Diarrhea.
- Trouble sleeping.
- Cough.
- Muscle pain.
- Feeling irritable.

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.

All products:

- Take with or without food.
- Do not take antacids within 4 hours before or 4 hours after taking this drug.
- If you take cimetidine, dexlansoprazole, esomeprazole, famotidine, lansoprazole, nizatidine, omeprazole, pantoprazole, rabeprazole, or ranitidine, ask your doctor or pharmacist how to take it with this drug.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- It is important that you do not miss or skip a dose of this drug during treatment.

Tablets:

- If you have trouble swallowing, talk with your doctor.

Oral pellets:

- Do not open until you are ready to use.
- This drug may be put right into your mouth. Do not chew the pellets. If taken with food, sprinkle the pellets on 1 or more spoonfuls of non-acidic soft food like pudding, chocolate syrup, mashed potato, or ice cream. The soft food needs to be at or below room temperature. Swallow without chewing.
- Take your dose within 30 minutes after mixing. Throw away any part not used within 30 minutes of mixing.

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.
- If you are not sure what to do if you miss a dose, call your doctor.

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

- Store in the original container at room temperature.
- 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.

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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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