PATIENT & CAREGIVER EDUCATION

Simeprevir

This information from Lexicomp® 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.

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 long-term hepatitis C infections.

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

- If you have an allergy to simeprevir 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 ever had liver problems other than hepatitis C.
- If you are **not** taking other drugs to treat hepatitis C.
- 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, or seizures. 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?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- If you have a sulfa (sulfonamide) allergy, talk with your doctor.
- If you are of East- or Southeast Asian descent, talk with your doctor. You may need a lower starting dose of this drug.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Avoid grapefruit and grapefruit juice.
- You may get sunburned more easily. Avoid sun, sunlamps, and tanning beds. Use sunscreen and wear clothing and eyewear that protects you from the sun.
- Very bad skin reactions to sunlight have happened with this drug. Sometimes, this has led to need to go to the hospital. Talk with the doctor.
- Slow heartbeat and the need to get a pacemaker have happened when amiodarone was given with sofosbuvir and certain other hepatitis C drugs. Sometimes, this has been deadly. Slow heartbeat has happened up to 2 weeks after starting hepatitis C treatment. You will

need to be watched closely if you will be taking amiodarone with hepatitis C treatment. Follow what your doctor has told you to do. Call your doctor right away if you have signs of slow heartbeat like chest pain, confusion, dizziness, passing out or near-passing out, memory problems, shortness of breath, tiredness, or weakness.

- This drug does not stop the spread of diseases like HIV or 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.
- This drug must be taken with other drugs to treat hepatitis C. Be sure you know about the warnings, benefits, and risks of the other drugs. Talk with your doctor if you have questions or concerns about any of your drugs used to treat hepatitis C.
- If you stop taking any of your other drugs to treat hepatitis C, talk with your doctor. You may need to stop taking this drug also.
- Use birth control that you can trust to prevent pregnancy while taking this drug.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.

- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

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.
- Shortness of breath.
- Red, blistered, or swollen skin.
- Very bad skin irritation.
- Mouth sores.
- Eye irritation.
- Severe and sometimes deadly liver problems have happened with this drug. Call your doctor right away

if you have 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:

- Itching.
- Upset stomach.
- Muscle pain.
- Diarrhea.
- Dizziness.
- Headache.
- Feeling tired or weak.
- Not able to sleep.

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 this drug with food.
- Swallow whole. Do not chew, open, or crush.
- Take this drug at the same time of day.
- 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.

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.
- 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.
- 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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If you have any questions, contact a member of your care team directly. If you're a patient at MSK and you need to reach a provider after 5 p.m., during the weekend, or on a holiday, call 212-639-2000.

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

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