Simeprevir oral capsule
MEDICATION GUIDE

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine talk to your doctor, pharmacist, or health care provider.

What is this medicine?
SIMEPREVIR (sim E pre vir) is an antiviral medicine. It is used with peginterferon alfa and ribavirin to treat hepatitis C. It will not work for colds, flu, or other viral infections.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?
Take this medicine by mouth with a full glass of water. Follow the directions on the prescription label. Do not cut, crush or chew this medicine. Take this medicine with food. Take your medicine at regular intervals. Do not take your medicine more often than directed. Take all of your medicine as directed even if you think you are better. Do not skip doses or stop your medicine early.

Talk to your pediatrician regarding the use of this medicine in children. Special care may be needed.

Overdosage: If you think you've taken too much of this medicine contact a poison control center or emergency room at once.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.

NOTE: This medicine is only for you. Do not share this medicine with others.

What if I miss a dose?
If you miss a dose, take it as soon as you can. If your next dose is to be taken in less than 12 hours, then do not take the missed dose. Take the next dose at your regular time. Do not take double or extra doses.

What should I tell my health care provider before I take this medicine?
They need to know if you have any of these conditions:
• East Asian descent
• Man with a partner who is pregnant or trying to get pregnant
• Organ transplant
• Other liver disease
• Prolonged exposure to sunlight
• An unusual or allergic reaction to simeprevir, ribavirin, interferons, other medicines, foods, dyes, or preservatives
• Pregnant or trying to get pregnant
• Breast-feeding

What may interact with this medicine?
• Certain antibiotics like clarithromycin, erythromycin, telithromycin, rifabutin, rifampin, rifapentine
• Certain antiviral medicines for HIV or AIDS like atazanavir, cobicistat; elvitegravir; emtricitabine; tenofovir, darunavir, delavirdine, efavirenz, etravirine, fosamprenavir, indinavir, lopinavir; ritonavir, nelfinavir, nevirapine, ritonavir, saquinavir, tipranavir
• Certain medicines for blood pressure like amlodipine, diltiazem, felodipine, nicardipine, nifedipine, nisoldipine, verapamil
• Certain medicines for cholesterol like atorvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, simvastatin
• Certain medicines for erectile dysfunction like sildenafil, tadalafil, vardenafil
• Certain medicines for fungal infections like fluconazole, itraconazole, ketoconazole, posaconazole, voriconazole
• Certain medicines for irregular heart beat like amiodarone, disopyramide, flecainide, mexiletine, propafenone, quinidine
• Certain medicines for seizures like carbamazepine, oxcarbazepine, phenobarbital, phenytoin
• Cispride
• Cyclosporine
• Dexamethasone
• Digoxin
• Midazolam
• Milk thistle
• Sirolimus
• St. John’s Wort
• Tacrolimus
• Triazolam
• Warfarin

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?
Side effects that you should report to your doctor or health care professional as soon as possible:
• Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
• Sensitivity to light

Side effects that usually do not require medical attention
[Report these to your doctor or health care professional if they continue or are bothersome.):
• Breathing problems
• Itching
• Muscle pain
• Nausea
• Rash

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I watch for while using this medicine?
See your doctor or health care professional for a follow-up visit as directed. You may need blood work while you are taking this medicine. Tell your doctor if your symptoms do not improve or if they get worse.

This medicine must be given with ribavirin. Ribavirin may cause birth defects or death to an unborn child. Women taking this medicine must avoid pregnancy while taking this medicine and for 6 months after stopping this medicine. Men who are taking this medicine must avoid getting a woman pregnant while taking this medicine and for 6 months after stopping this medicine. Use 2 forms of birth control. Women who can still have children must have a negative pregnancy test before starting treatment. Take monthly pregnancy tests while you are taking this medicine and for 6 months after this medicine is stopped. Talk to your doctor if you think that you or your partner are pregnant or are trying to become pregnant.

This medicine can make you more sensitive to the sun. Keep out of the sun. If you cannot avoid being in the sun, wear protective clothing and use sunscreen. Do not use sun lamps or tanning beds/booths.

Where should I keep my medicine?
Keep out of the reach of children.
Store at room temperature below 30 degrees C [86 degrees F].
Throw away any unused medicine after the expiration date.

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.