



# SIMEPREVIR (Olysio)

## WHAT IS SIMEPREVIR?

Simeprevir is a drug used as part of antiviral therapy against hepatitis C virus (HCV). The trade name in North America is Olysio. During its development it was called TMC435. It is manufactured by Janssen Pharmaceuticals.

Simeprevir is an HCV protease inhibitor. These drugs prevent the protease enzyme from working. This makes it harder for the virus to multiply. See Step 6 of the HCV life cycle shown in Fact Sheet 670.

Simeprevir directly interferes with the HCV life cycle. Earlier drugs used to treat HCV were interferon and ribavirin (see fact sheet 680.) They are primarily general immune boosters. Simeprevir must be used in combination with pegylated interferon and ribavirin (pegIFN/RBV). It should not be used by itself.

## WHO SHOULD TAKE IT?

Simeprevir was approved in 2013 as an antiviral drug for people infected with HCV genotype 1 whose liver is still functioning. People with decompensated (unstable) liver cirrhosis, should not take simeprevir. Signs of decompensated cirrhosis may include bleeding due to varices (swelling veins) in the throat and stomach, ascites (accumulation of fluid in the abdomen) or encephalopathy (brain damage that causes personality changes or problems thinking).

Simeprevir has not been studied in people less than 18 years old, or in liver transplant patients. There is limited information on people who are also infected with HIV or with hepatitis B.

Taking simeprevir along with pegIFN/RBV gives you a much better chance of clearing HCV genotype 1 infection than just taking pegIFN/RBV.

## WHAT ABOUT DRUG RESISTANCE?

Some new copies of HCV carry mutations, meaning they are slightly different from the original virus. Some mutated virus can keep multiplying even when you are taking anti-HCV

medications. When this happens, the drug will stop working. This is called "developing resistance" to the drug.

**Resistance can develop quickly. It is very important to take antiviral medications according to instructions, on schedule, and not to skip or reduce doses.**

If your HCV viral load is too high after 4 weeks of treatment, your doctor might decide that you should stop taking simeprevir to avoid having your HCV develop resistance.

## HOW IS IT TAKEN?

Simeprevir is taken once daily by mouth as a 150 mg (mg) capsule..

Simeprevir must be taken with pegIFN/RBV. Interferon is injected under the skin, and ribavirin is taken by mouth. Fact sheet 680 has more information on these medications.

Simeprevir use is based on "response guided therapy." The length of treatment depends on how well it controls HCV viral load early in treatment.

In most cases, simeprevir is taken for 12 weeks. Treatment continues with pegIFN/RBV. Patients who have a good response to simeprevir continue treatment for an additional 12 weeks. Other patients take pegIFN/RBV for 36 weeks, for a total of 48 weeks of treatment. Treatment has failed if viral load is over 1000 units per milliliter at week 4. If this occurs, simeprevir should be stopped.

Simeprevir must be taken with food. This increases blood levels of the drug. Simeprevir needs some fat for good absorption. Do not take it with a fat-free or low fat meal. Simeprevir should be stored at room temperature.

## WHAT ARE THE SIDE EFFECTS?

Simeprevir can cause a reduction of red blood cell counts (anemia, see fact sheet 552.) An important side effect is skin rash which may occur in over half of all patients. Sun light exposure can trigger or worsen rash. Sun protection with sunscreen and clothing is recommended.

Other common side effects of simeprevir include itching, nausea, diarrhea (see fact sheet 554), and vomiting.

Because simeprevir is always taken in combination with ribavirin, which can cause serious birth defects, do not take simeprevir if you or your sexual partner are pregnant or wants to become pregnant. Do not become pregnant for 6 months after you or your partner stop taking simeprevir combination treatment.

See fact sheet 680 for more information on the side effects of interferon and ribavirin.

Be sure to tell your health care provider about any side effects that you are having.

## HOW DOES IT REACT WITH OTHER DRUGS?

Simeprevir combination therapy can affect how other drugs are processed by the liver. **This can change the amount of each drug in your bloodstream and cause an under- or overdose.**

Drugs to watch out for include antiretrovirals used for HIV, drugs to treat high cholesterol (statins), rifampin to treat tuberculosis, drugs for erectile dysfunction, antifungal "azole" drugs, drugs to treat high blood pressure, antibiotics, sedatives (benzodiazepines) antidepressants, hormonal contraceptives and others.

The herb **St. John's Wort** (See Fact Sheet 729) lowers the blood levels of some protease inhibitors. Do not take it while taking simeprevir.

**New drug interactions are being identified all the time. Make sure that your health care provider knows about ALL drugs and supplements you are taking.**

Reviewed December 9, 2014