

The goal of hepatitis C virus (HCV) treatment is a cure (when there is no hepatitis C virus in a person's bloodstream at least 12 weeks after treatment is finished).

What is Olysio? Olysio (simeprevir) is an HCV-fighting drug. It must be used with other drugs to treat hepatitis C. In the United States, Olysio is approved for people with hepatitis C genotype 1 who are over 18 years old.

How is Olysio used? Olysio is taken once daily, with food, for 12 or 24 weeks. The type and length of treatment depends on HCV treatment history, whether a person has cirrhosis, and the other HCV drugs used with Olysio.

Hepatitis C treatment is changing quickly. Although Olysio was approved for use with pegylated interferon (PEG-IFN) and ribavirin (RBV), it is being studied and used with other drugs in interferon-free combinations.

U.S. HCV treatment guidelines list Olysio and PEG-IFN, or Olysio and **Sovaldi**, with or without **RBV**, as alternative treatments for genotype 4 in people being treated for the first time.

Olysio: Treatment Length and Cure Rates from Clinical Trials and Real-World Settings*

Genotype 1, never treated for HCV, no cirrhosis	+ Cirrhosis
Olysio + Sovaldi (with or without RBV), 12 weeks: 95% (in a small trial; real-world: 88% to 92%)	Olysio + Sovaldi (with or without RBV), 24 weeks: 100% (real-world: 75% to 87%)
Genotype 1, treatment-experienced, no cirrhosis	+ Cirrhosis
Olysio + Sovaldi (with or without RBV), 12 weeks: 95% (real-world: 81% to 87%)	Olysio + Sovaldi (with or without RBV), 24 weeks: 95% (real-world: 76% to 79%)

*Cure rates in clinical trials are higher than in real life since the people in them are usually healthier and get extra monitoring and support. These results came from a small trial (fewer than 200 people); Olysio and Sovaldi are being studied in larger trials.

The most important thing a person can do to be cured is not to miss taking doses of HCV treatment—called **adherence**. Adherence lowers the risk for drug resistance.

What is drug resistance? Each day, HCV makes billions of copies of itself. Some of these copies are not the same as the original virus. They may have changes that can stop hepatitis C drugs from working (called **drug resistance**). If people miss doses of their treatment, the virus gets a chance to reproduce—and some of these copies can be resistant to HCV treatment.

Some people have drug resistance even though they have never been on hepatitis C treatment—but many can be cured anyway.

Most people who are not cured have resistance to one or more of the HCV drugs they've taken. Sometimes, resistance disappears within months. Resistance may pop back up if hepatitis C is re-treated with the same drug—or another drug from the same family. No one is sure how long HCV drug resistance lasts, or whether it will make it harder to re-treat hepatitis C.

Olysio and age, gender, and race/ethnicity: In real-world settings, cure rates did not differ by age (over 65 vs. under 65) in people treated with Olysio and Sovaldi (with or without RBV). Real-world cure rates were slightly higher in women than men. There is not much information from clinical trials of Olysio and Sovaldi by race or ethnicity because most people in the trials were white. In real-world reports, there was no difference in cure rates between black people and nonblack people. Drug levels of Olysio are higher in people of Asian ancestry; this may worsen their side effects.

Side effects from Olysio: Olysio can cause photosensitivity (severe sunburn, blistering). Limit exposure to sunlight, tanning beds, and sunlamps while using Olysio, and wear a hat, sunglasses, sunscreen, and protective clothing. If sunburn or rash occur, consult your health care provider immediately. In a clinical trial of Olysio and Sovaldi, the most common side effects were fatigue, headache, nausea, dizziness, diarrhea, insomnia, rash, and sensitivity to light. **Olysio can cause rash**, especially during the first four weeks of treatment. Consult your health care provider immediately if you have mouth sores or red and swollen eyes.

Does Olysio work for HIV-positive people? With PEG-IFN and RBV, Olysio was just as effective for people with HIV. There are no clinical trials of Olysio and Sovaldi (with or without RBV) in HIV/HCV, but cure rates have been the same among coinfecting people treated in real-world settings.

Olysio can be used with these HIV drugs: Isentress (raltegravir), Selzentry (maraviroc), Fuzeon (enfuvirtide), Edurant (rilpivirine), Epivir (lamivudine), Ziagen (abacavir), Viread (tenofovir), Emtriva (emtricitabine), and Truvada (emtricitabine and tenofovir disoproxil fumarate).

Olysio and other medications: drug-drug interactions: Olysio should not be used with certain drugs. Combining medications can increase or lower drug levels (called **drug-drug interactions**). Increasing drug levels can make side effects from each drug worse. If drug levels get too low, a drug can stop working, putting people at risk for drug resistance or not being cured. **Talk with your health care provider about starting or stopping any medications, supplements, or herbal remedies.**

Some drugs should be switched, stopped, or avoided while using Olysio. More information is available in Olysio's prescribing information (<https://www.olsyio.com/shared/product/olsyio/prescribing-information.pdf>) and at:

www.hep-druginteractions.org.

Storing Olysio: Store Olysio at room temperature (under 86°F). Keep Olysio in the same bottle it came in to protect it from light.

Olysio in people with kidney disease: Olysio can be used by people with mild or moderate kidney disease. People with severe kidney disease should consult with a specialist before using Olysio. It has not been studied in people on dialysis.

Olysio in people with cirrhosis: Hepatitis C treatment guidelines recommend that people with serious liver damage (Child-Pugh Class B or C cirrhosis) be treated by a specialist. Olysio is **not recommended** for people with Child-Pugh Class C cirrhosis.

Olysio during pregnancy, nursing, and in children: In animal studies, high doses of Olysio caused birth defects. Since it is not known whether Olysio will harm unborn babies, it should be used during pregnancy only if the potential benefits of HCV treatment outweigh the risks.

In animal studies, Olysio was found in breast milk—and it harmed breast-fed baby rats. It is not known whether Olysio passes into human breast milk, but nursing mothers should decide whether to stop breast-feeding or discontinue treatment with Olysio to avoid potential risk to their infants.

RBV causes birth defects and miscarriage. RBV should not be used by pregnant women or by male partners of pregnant women. RBV stays in a person's body for months, so women and their male partners should avoid pregnancy until six months **after** stopping it. Using two forms of birth control to prevent pregnancy while taking RBV—and for six months afterward—is recommended (for more information, see TAG's **ribavirin** fact sheet).

It is not clear whether RBV passes into breast milk. Nursing is not recommended while taking RBV.

Olysio has not been studied in children, and it is not approved for people under 18 years old.

Access to Olysio may be restricted by public and private payers. The criteria differ depending on the type of coverage and the state it is issued in. People with private insurance may be eligible for assistance with copayments. Uninsured people may be eligible for medication at no charge.

Janssen's patient assistance program is called Olysio Support. Information is available by phone, at 1.855.565.9746, Monday through Friday between 8:00 a.m. and 8:00 p.m. (Eastern Time), or online at: <http://www.janssenprescriptionassistance.com/olsyio-cost-assistance>.

This fact sheet is current as of November 2015. Always check for updated information.