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2. Olysio

# Olysio

Generic name: simeprevir [ sim-E-pre-vir ]

Drug class: Protease inhibitors

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## What is Olysio?

Olysio is an antiviral medicine that prevents certain viruses from multiplying in your body. Simeprevir is used in combination with other medications to treat chronic hepatitis C in adults.

Olysio treats specific genotypes of hepatitis C, and only in certain people. Use only the medications prescribed for you. Do not share your medicine with other people.

Olysio must be given in combination with other antiviral medications and it should not be used alone.

Olysio is sometimes used in people who also have HIV. This medicine is not a treatment for HIV or AIDS.

## Warnings

If you have ever had hepatitis B, Olysio can cause this condition to come back or get worse. You will need frequent blood tests to check your liver function.

Olysio is used in combination with other medications. **Read the medication guide or patient instructions provided** with each medication in your combination therapy. Do not change your doses or medication schedule without your doctor's advice.

Call your doctor right away if you have **symptoms of liver problems:** vomiting, loss of appetite, feeling weak or tired, clay-colored stools, or jaundice (yellowing of the skin or eyes).

Avoid exposure to sunlight or tanning beds. Sunlight can cause a severe rash or skin reaction while you are using simeprevir combination treatment. Use sunscreen and wear a hat, sunglasses, and protective clothing when you are outdoors.

## Before taking this medicine

You should not use Olysio if you are allergic to simeprevir. **If you take Olysio with other antiviral medicines**: There may be other reasons you should not take this combination treatment. Tell your doctor about all your medical conditions.

Your doctor will perform blood tests to make sure Olysio is the right treatment for your condition.

To make sure this medicine is safe for you, tell your doctor if you have ever had:

- · hepatitis B;
- liver problems other than hepatitis, or if you have had a liver transplant;
- if you are receiving phototherapy (light therapy);
- if you have recently used a heart rhythm medicine called amiodarone (Cordarone, Nexterone, Pacerone); or
- if you use a blood thinner (warfarin, Coumadin, Jantoven) and you have routine "INR" or prothrombin time tests.

Olysio is sometimes used in combination with ribavirin. Ribavirin can cause birth defects or death in an unborn baby.

- If you are a woman, do not use ribavirin if you are pregnant. You may need to have a negative pregnancy test before taking ribavirin and every month during your treatment.
- If you are a man, do not use ribavirin if your sexual partner is pregnant. An unborn baby could be harmed if you have sex with a pregnant woman while you are taking ribavirin.

While taking simeprevir with ribavirin, use at least 2 effective forms of birth control to prevent pregnancy, whether you are a man or a woman. Ribavirin use by either parent may cause birth defects.

Keep using 2 forms of birth control for at least 6 months after your last dose of ribavirin. Tell your doctor right away if a pregnancy occurs while either the mother or the father is using ribavirin.

It is not known whether simeprevir passes into breast milk or if it could harm a nursing baby. You should not breast-feed while using this medicine.

Olysio is not approved for use by anyone younger than 18 years old.

① Olysio pregnancy and breastfeeding warnings (more detail)

## How should I take Olysio?

Take Olysio exactly as prescribed by your doctor. Follow all directions on your prescription label. Do not take this medicine in larger or smaller amounts or for longer than recommended.

Take with food.

Do not crush, chew, break, or open a Olysio capsule. Swallow the capsule whole.

You will need frequent blood tests to check your liver function.

If you have ever had hepatitis B, simeprevir can cause this condition to come back or get worse. You will need liver function tests during treatment and for several months after you stop using this medicine.

Read the medication guide or patient instructions provided with each medication in your combination therapy. Do not change your doses or medication schedule without your doctor's advice. Every person with chronic hepatitis C should remain under the care of a doctor.

You should not stop using Olysio suddenly. Stopping suddenly could make your condition harder to treat with

hepatitis C antiviral medicine.

Store at room temperature away from moisture, heat, and light.

1 Detailed Olysio dosage information

## What happens if I miss a dose?

Take the missed dose as soon as you remember. If you are more than 12 hours late, skip the missed dose. Do not take extra medicine to make up the missed dose.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

### What to avoid

Avoid exposure to sunlight or tanning beds. Simeprevir combination treatment can make your skin more sensitive to sunlight, especially during the first 4 weeks of treatment. This may cause a severe sunburn or skin rash. Wear a hat, sunglasses, and protective clothing and use sunscreen (SPF 30 or higher) when you are outdoors.

Avoid taking an herbal supplement containing St. John's wort at the same time you are taking Olysio.

## Olysio side effects

Get emergency medical help if you have **signs of an allergic reaction to Olysio:** hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Read all of your medication guides to learn about possible side effects of other medications you use in combination with simeprevir. Ask your doctor or pharmacist if you have any questions.

Call your doctor at once if you have:

- new or worsening liver symptoms, such as vomiting, loss of appetite, feeling weak or tired, clay-colored stools, or yellowing of the skin or eyes;
- severe skin rash (redness, swelling, burning, blistering);
- eye redness or puffiness;
- · mouth sores; or
- · shortness of breath.

If you take Olysio and you also take a heart rhythm medicine called amiodarone: This combination of medicines can cause dangerous side effects on your heart. Get medical help right away if you take these medicines and you have:

- very slow heartbeats, chest pain, shortness of breath;
- · confusion, memory problems; or
- weakness, extreme tiredness, light-headed feeling (like you might pass out).

Common Olysio side effects may include:

- · mild itching or rash;
- nausea; or
- · headache.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Olysio side effects (more detail)

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## What other drugs will affect Olysio?

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective.

Other drugs may interact with simeprevir, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all your current medicines and any medicine you start or stop using.

1 Olysio drug interactions (more detail)

## Does Olysio interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.



## **Popular FAQ**

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## More about Olysio (simeprevir)

- Check interactions
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- During pregnancy
- FDA approval history
- Drug class: protease inhibitors

Breastfeeding

### **Professional resources**

• Olysio prescribing information

## Related treatment guides

· Hepatitis C

### **Further information**

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Olysio only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

#### Medical Disclaimer

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#### **DRUG STATUS**

Availability



**Pregnancy & Lactation** 

ঝ্য Risk data available

**CSA Schedule\*** 

N/A Not a controlled drug

**Approval History** 

10+ years FDA approved 2013

### **User Reviews & Ratings**

4 Reviews

#### **Images**

Olysio 150 mg (TMC435 150)

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