

PATIENT INFORMATION

OLYSIO® (oh li see oh)

(simeprevir)
capsules

Read this Patient Information before you start taking OLYSIO and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

Important: You should not take OLYSIO alone. OLYSIO should be used together with other antiviral medicines to treat chronic hepatitis C virus infection. **When taking OLYSIO in combination with peginterferon alfa and ribavirin you should also read those Medication Guides.** When taking OLYSIO in combination with sofosbuvir, you should also read its Patient Information leaflet.

What is the most important information I should know about OLYSIO?

OLYSIO can cause serious side effects, including:

Hepatitis B virus reactivation: Before starting treatment with OLYSIO, your healthcare provider will do blood tests to check for hepatitis B virus infection. If you have ever had hepatitis B virus infection, the hepatitis B virus could become active again during or after treatment of hepatitis C virus with OLYSIO. Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems including liver failure and death. Your healthcare provider will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop taking OLYSIO.

OLYSIO combination treatment with sofosbuvir (Sovaldi®) may result in slowing of the heart rate (pulse) along with other symptoms when taken with amiodarone (Cordarone®, Nexterone®, Pacerone®), a medicine used to treat certain heart problems.

OLYSIO combination treatment with sofosbuvir (Sovaldi®) may result in slowing of the heart rate (pulse) along with other symptoms when taken with amiodarone (Cordarone®, Nexterone®, Pacerone®), a medicine used to treat certain heart problems.

- If you are taking OLYSIO with sofosbuvir and amiodarone and you get any of the following symptoms, or if you have a slow heart rate call your healthcare provider right away:
 - fainting or near-fainting
 - dizziness or lightheadedness
 - weakness, extreme tiredness
 - chest pain, shortness of breath
 - confusion or memory problems

OLYSIO may cause severe liver problems in some people. These severe liver problems may lead to liver failure or death.

- Your healthcare provider may do blood tests to check your liver function during treatment with OLYSIO.
- Your healthcare provider may tell you to stop taking OLYSIO if you develop signs and symptoms of liver problems.
- Tell your healthcare provider right away if you develop any of the following symptoms, or if they worsen during treatment with OLYSIO:
 - tiredness
 - weakness
 - loss of appetite
 - nausea and vomiting
 - yellowing of your skin or eyes
 - color changes in your stools

OLYSIO combination treatment may cause rashes and skin reactions to sunlight. These rashes and skin reactions to sunlight can be severe and you may need to be treated in a hospital. Rashes and skin reactions to sunlight are most common during the first 4 weeks of treatment, but can happen at any time during combination treatment with OLYSIO.

- Limit sunlight exposure during treatment with OLYSIO.
- Use sunscreen and wear a hat, sunglasses, and protective clothing during treatment with OLYSIO.
- Avoid use of tanning beds, sunlamps, or other types of light therapy during treatment with OLYSIO.
- Call your healthcare provider right away if you get any of the following symptoms:
 - burning, redness, swelling or blisters on your skin
 - mouth sores or ulcers
 - red or inflamed eyes, like “pink eye” (conjunctivitis)

For more information about side effects, see the section “What are the possible side effects of OLYSIO?”

What is OLYSIO?

- OLYSIO is a prescription medicine used with other antiviral medicines to treat chronic (lasting a long time) hepatitis C virus genotype 1 or 4 infection. **OLYSIO should not be taken alone.**
- **OLYSIO is not for people with certain types of liver problems.**

It is not known if OLYSIO is safe and effective in children under 18 years of age.

What should I tell my healthcare provider before taking OLYSIO?

Before taking OLYSIO, tell your healthcare provider about all of your medical conditions, including if you:

- have ever had hepatitis B virus infection
- have liver problems other than hepatitis C virus infection
- have ever taken any medicine to treat hepatitis C virus infection
- had a liver transplant
- are receiving phototherapy
- have any other medical condition
- are pregnant or plan to become pregnant. It is not known if OLYSIO will harm your unborn baby. Do not take OLYSIO in combination with ribavirin if you are pregnant, or your sexual partner is pregnant.
 - **Females who take OLYSIO in combination with ribavirin should avoid becoming pregnant during treatment and for 6 months after stopping ribavirin. Call your healthcare provider right away if you think you may be pregnant or become pregnant during treatment with OLYSIO in combination with ribavirin.**
 - **Males and females who take OLYSIO with ribavirin should read the ribavirin Medication Guide for important pregnancy, contraception, and infertility information.**
- are breastfeeding. It is not known if OLYSIO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with OLYSIO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may interact with OLYSIO. This can cause you to have too much or not enough OLYSIO or other medicines in your body, which may affect the way OLYSIO or your other medicines work, or may cause side effects. Keep a list of your medicines and show it to your healthcare provider and pharmacist.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with OLYSIO.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take OLYSIO with other medicines.

How should I take OLYSIO?

- Take OLYSIO exactly as your healthcare provider tells you to take it. Do not change your dose unless your healthcare provider tells you to.
- Do not stop taking OLYSIO unless your healthcare provider tells you to. If you think there is a reason to stop taking OLYSIO, talk to your healthcare provider before doing so.
- Take 1 OLYSIO capsule each day with food.
- Swallow OLYSIO capsules whole.
- It is important that you do not miss or skip doses of OLYSIO during treatment.
- Do not take two doses of OLYSIO at the same time to make up for a missed dose.
- If you take too much OLYSIO, call your healthcare provider right away or go to the nearest hospital emergency room.

What are the possible side effects of OLYSIO?

OLYSIO can cause serious side effects, including:

- Hepatitis B virus reactivation. See “What is the most important information I should know about OLYSIO?”

The most common side effects of OLYSIO when used in combination with sofosbuvir include:

- tiredness
- headache
- nausea

The most common side effects of OLYSIO when used in combination with peginterferon alfa and ribavirin include:

- skin rash
- itching
- nausea

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of OLYSIO. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store OLYSIO?

- Store OLYSIO at room temperature below 86°F (30°C).
- Store OLYSIO in the original bottle to protect it from light.

Keep OLYSIO and all medicines out of the reach of children.

General information about the safe and effective use of OLYSIO

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use OLYSIO for a condition for which it was not prescribed. Do not give your OLYSIO to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information about OLYSIO, talk with your pharmacist or healthcare provider. You can ask your pharmacist or healthcare provider for information about OLYSIO that is written for health professionals.

For more information about OLYSIO, go to www.OLYSIO.com or call 1-800-526-7736.

What are the ingredients in OLYSIO?

Active ingredient: simeprevir

Inactive ingredients: colloidal anhydrous silica, croscarmellose sodium, lactose monohydrate, magnesium stearate, sodium lauryl sulphate. The white capsule contains gelatin and titanium dioxide (E171) and is printed with ink containing iron oxide black (E172) and shellac (E904).

Product of Belgium

Manufactured by: Janssen-Cilag SpA, Latina, Italy

Manufactured for: Janssen Therapeutics, Division of Janssen Products, LP, Titusville NJ 08560

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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