

Anemia

The most common adverse event associated with ribavirin is anemia, which may be severe [*see Boxed Warning, Warnings and Precautions (5.2) and Adverse Reactions (6.1)*]. Patients should be advised that laboratory evaluations are required prior to starting COPEGUS therapy and periodically thereafter [*see Warnings and Precautions (5.9)*]. It is advised that patients be well hydrated, especially during the initial stages of treatment.

Patients who develop dizziness, confusion, somnolence, and fatigue should be cautioned to avoid driving or operating machinery.

Patients should be advised to take COPEGUS with food.

Patients should be questioned about prior history of drug abuse before initiating COPEGUS/PEGASYS, as relapse of drug addiction and drug overdoses have been reported in patients treated with interferons.

Patients should be advised not to drink alcohol, as alcohol may exacerbate chronic hepatitis C infection.

Patients should be informed about what to do in the event they miss a dose of COPEGUS. The missed doses should be taken as soon as possible during the same day. Patients should not double the next dose. Patients should be advised to call their healthcare provider if they have questions.

Patients should be informed that the effect of PEGASYS/COPEGUS treatment of hepatitis C infection on transmission is not known, and that appropriate precautions to prevent transmission of hepatitis C virus during treatment or in the event of treatment failure should be taken.

Patients should be informed regarding the potential benefits and risks attendant to the use of COPEGUS. Instructions on appropriate use should be given, including review of the contents of the enclosed MEDICATION GUIDE, which is not a disclosure of all or possible adverse effects.

MEDICATION GUIDE

COPEGUS[®] (Co-PEG-UHS)

(ribavirin)

Tablets

Read this Medication Guide carefully before you start taking COPEGUS and read the Medication Guide each time you get more COPEGUS. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Also read the Medication Guide for PEGASYS (peginterferon alfa-2a).

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

- 1. You should not take COPEGUS alone to treat chronic hepatitis C infection.** COPEGUS should be used with PEGASYS to treat chronic hepatitis C infection.
- 2. COPEGUS may cause you to have a blood problem (hemolytic anemia) that can worsen any heart problems you have, and cause you to have a heart attack or die.** Tell your healthcare provider if you have ever had any heart problems. COPEGUS may not be right for you. If you have chest pain while you take COPEGUS, get emergency medical attention right away.
- 3. COPEGUS may cause birth defects or death of your unborn baby.** If you are pregnant or your sexual partner is pregnant, do not take COPEGUS. You or your sexual partner should not become pregnant while

you take COPEGUS and for 6 months after treatment is over. You must use two forms of birth control when you take COPEGUS and for the 6 months after treatment.

- Females must have a pregnancy test before starting COPEGUS, every month while treated with COPEGUS, and every month for the 6 months after treatment with COPEGUS.
- **If you or your female sexual partner becomes pregnant** while taking COPEGUS or within 6 months after you stop taking COPEGUS, tell your healthcare provider right away. You or your healthcare provider should contact the **Ribavirin Pregnancy Registry by calling 1-800-593-2214**. The Ribavirin Pregnancy Registry collects information about what happens to mothers and their babies if the mother takes COPEGUS while she is pregnant.

What is COPEGUS?

COPEGUS is a medicine used with another medicine called PEGASYS (peginterferon alfa-2a) to treat chronic (lasting a long time) hepatitis C infection in people whose liver still works normally, and who have not been treated before with a medicine called an interferon alpha. It is not known if COPEGUS is safe and will work in children under 18 years of age.

Who should not take COPEGUS?

See “**What is the most important information I should know about COPEGUS?**”

Do not take COPEGUS if you:

- **have certain types of hepatitis** caused by your immune system attacking your liver (autoimmune hepatitis)
- **have certain blood disorders, such as thalassemia major or sickle-cell anemia (hemoglobinopathies)**
- **take didanosine (Videx or Videx EC)**

Talk to your healthcare provider before starting treatment with COPEGUS if you have any of these medical conditions.

What should I tell my healthcare provider before taking COPEGUS?

Before you take COPEGUS, tell your healthcare provider if you have or have had:

- **treatment for hepatitis C that did not work for you**
- **serious allergic reactions to COPEGUS or to any of the ingredients in COPEGUS.** See the end of this Medication Guide for a list of ingredients.
- **breathing problems.** COPEGUS may cause or worsen your breathing problems you already have.
- **vision problems.** COPEGUS may cause eye problems or worsen eye problems you already have. You should have an eye exam before you start treatment with COPEGUS.
- **certain blood disorders such as anemia**
- **high blood pressure, heart problems or have had a heart attack.** Your healthcare provider should test your blood and heart before you start treatment with COPEGUS.
- **thyroid problems**
- **diabetes.** COPEGUS and PEGASYS combination therapy may make your diabetes worse or harder to treat.
- **liver problems** other than hepatitis C virus infection
- **human immunodeficiency virus (HIV) or other immunity problems**
- **mental health problems,** including depression or thoughts of suicide
- **kidney problems**
- **an organ transplant**
- **drug addiction or abuse**
- **infection with hepatitis B virus**
- **any other medical condition**
- **are breast feeding.** It is not known if COPEGUS passes into your breast milk. You and your healthcare provider should decide if you will take COPEGUS or breast-feed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Some medicines can cause serious side effects if taken while you also take COPEGUS. Some medicines may affect how COPEGUS works or COPEGUS may affect how your other medicines work.

Especially tell your healthcare provider if you take any medicines to treat HIV, including didanosine (Videx or Videx EC), or if you take azathioprine (Imuran or Azasan).

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take COPEGUS?

- Take COPEGUS exactly as your healthcare provider tells you. Your healthcare provider will tell you how much COPEGUS to take and when to take it.
- Take COPEGUS with food.
- If you miss a dose of COPEGUS, take the missed dose as soon as possible during the same day. Do not double the next dose. If you have questions about what to do, call your healthcare provider.
- If you take too much COPEGUS, call your healthcare provider or local Poison Control Center right away, or go the nearest hospital emergency room right away.
- Your healthcare provider should do blood tests before you start treatment with COPEGUS, at weeks 2 and 4 of treatment, and then as needed to see how well you are tolerating treatment and to check for side effects. Your healthcare provider may change your dose of COPEGUS based on blood test results or side effects you may have.
- If you have heart problems, your healthcare provider should check your heart by doing an electrocardiogram before you start treatment with COPEGUS, and if needed during treatment.

What should I avoid while taking COPEGUS?

- **COPEGUS can make you feel tired, dizzy, or confused. You should not drive or operate machinery if you have any of these symptoms.**
- **Do not drink alcohol**, including beer, wine, and liquor. This may make your liver disease worse.

What are the possible side effects of COPEGUS?

COPEGUS may cause serious side effects including:

See **“What is the most important information I should know about COPEGUS?”**

- **Swelling and irritation of your pancreas (pancreatitis).** You may have stomach pain, nausea, vomiting or diarrhea.
- **Severe allergic reactions.** Symptoms may include hives, wheezing, trouble breathing, chest pain, swelling of your mouth, tongue, or lips, or severe rash.
- **Serious breathing problems.** Difficulty breathing may be a sign of a serious lung infection (pneumonia) that can lead to death.
- **Serious eye problems** that may lead to vision loss or blindness.
- **Liver problems.** Some people may get worsening of liver function. Tell your healthcare provider right away if you have any of these symptoms: stomach bloating, confusion, brown urine, and yellow eyes.
- **Severe depression**
- **Suicidal thoughts and attempts**

Call your healthcare provider or get medical help right away if you have any of the symptoms listed above. These may be signs of a serious side effect of COPEGUS treatment.

Common side effects of COPEGUS taken with PEGASYS include:

- flu-like symptoms-feeling tired, headache, shaking along with high temperature (fever), and muscle or joint aches
- mood changes, feeling irritable, anxiety, and difficulty sleeping
- loss of appetite, nausea, vomiting, and diarrhea
- hair loss
- itching

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

These are not all the possible side effects of COPEGUS treatment. 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.

You may also report side effects to Genentech at 1-888-835-2555.

How should I store COPEGUS?

- Store COPEGUS tablets between 59°F and 86°F (15°C and 30°C).
- Keep the bottle tightly closed.

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

General information about the safe and effective use of COPEGUS

It is not known if treatment with COPEGUS in combination with PEGASYS will prevent an infected person from spreading the hepatitis C virus to another person while on treatment.

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

This Medication Guide summarizes the most important information about COPEGUS. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about COPEGUS that is written for healthcare professionals.

What are the ingredients in COPEGUS?

Active Ingredient: ribavirin

Inactive Ingredients: The core of the tablet contains pregelatinized starch, microcrystalline cellulose, sodium starch glycolate, cornstarch, and magnesium stearate. The coating of the tablet contains Chromatone-P or Opadry Pink (made by using hydroxypropyl methyl cellulose, talc, titanium dioxide, synthetic yellow iron oxide, and synthetic red iron oxide), ethyl cellulose (ECD-30), and triacetin.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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