

COPEGUS® (ribavirin, USP)

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MEDICATION GUIDE

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COPEGUS®

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(ribavirin, USP)

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TABLETS

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Read this Medication Guide carefully before you start taking COPEGUS (Co-PEG-UHS) 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.

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

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1. COPEGUS, a form of ribavirin, may cause birth defects or death of an unborn child. Therefore, if you are pregnant or your partner is pregnant or plans to become pregnant, do not take COPEGUS. Female patients and female partners of male patients being treated with COPEGUS must not become pregnant during treatment and for 6 months after treatment has stopped.

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During this time you must have pregnancy tests that show you are not pregnant. You must also use 2 effective forms of birth control during therapy and for 6 months after stopping therapy. Male patients should use a condom with spermicide as one of the two forms.

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If pregnancy occurs, report the pregnancy to your healthcare provider right away. (See “**What should I avoid while taking COPEGUS?**”.)

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If you or a female sexual partner becomes pregnant, you should tell your healthcare provider. There is a Ribavirin Pregnancy Registry that collects information about pregnancy outcomes of female patients and female partners of male patients exposed to ribavirin. You or your healthcare provider are encouraged to contact the Registry at 1-800-593-2214.

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2. COPEGUS can cause a dangerous drop in your red blood cell count. COPEGUS can cause anemia, which is a decrease in the number of red blood cells. This can be dangerous, especially if you have heart or breathing problems. This may cause a worsening of heart (cardiovascular) or circulatory problems. Some patients may get chest pain and rarely, a heart attack. Patients with a history of heart disease have the highest chance of this. Tell your healthcare provider, before taking COPEGUS if you have or have ever had any heart or breathing problems. Your healthcare provider should check your red blood cell count before you start treatment with COPEGUS and often during the first 4 weeks of treatment. Your red blood cell count may be done more often if you have any heart or breathing problems.

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3. Do not take COPEGUS alone to treat hepatitis C virus infection. COPEGUS does not treat hepatitis C virus infections by itself. COPEGUS should be used in combination with PEGASYS® (peginterferon alfa-2a) to treat continuing (chronic) hepatitis C virus infections. You should read the Medication Guide for PEGASYS

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690 because it has additional important information about treatment that is not covered in
691 this Medication Guide. Your healthcare provider or pharmacist should give you a
692 copy of the PEGASYS Medication Guide.

693 **What is COPEGUS?**

694 COPEGUS is the antiviral medicine ribavirin. It is used in combination with a medicine
695 called PEGASYS (peginterferon alfa-2a) to treat some adults with chronic hepatitis C
696 whose liver still works normally, and who have not been treated before with a medicine
697 called an interferon alpha. It is not known how COPEGUS and PEGASYS work together
698 to fight hepatitis C virus infections.

699 It is not known if treatment with COPEGUS and PEGASYS combination therapy can
700 cure hepatitis C or if it can prevent liver damage (cirrhosis), liver failure or liver cancer
701 that is caused by hepatitis C virus infections. It is not known if treatment with COPEGUS
702 and PEGASYS combination therapy will prevent an infected person from spreading the
703 hepatitis C virus to another person.

704 Treatment with COPEGUS has not been studied in children under 18 years of age.

705 **Who should not take COPEGUS?**

706 **Do not use COPEGUS if:**

- 707 • **You are a female and you are pregnant or plan to become pregnant** during
708 treatment or during the 6 months after your treatment has ended. (See “**What is the**
709 **most important information I should know about COPEGUS?**” and “**What**
710 **should I avoid while taking COPEGUS?**”.)
- 711 • **You are a male patient with a female sexual partner who is pregnant or plans to**
712 **become pregnant** at any time while you are being treated with COPEGUS or during
713 the 6 months after your treatment has ended. (See “**What is the most important**
714 **information I should know about COPEGUS?**” and “**What should I avoid while**
715 **taking COPEGUS?**”.)
- 716 • **You are breast feeding. We do not know if COPEGUS can pass through your**
717 **milk and if it can harm your baby. You will need to choose either to breast-feed**
718 **or take COPEGUS, but not both.**
- 719 • **You have a liver disease called autoimmune hepatitis** (hepatitis caused by your
720 immune system attacking your liver).
- 721 • **You have unstable or severe liver disease.**
- 722 • **You are allergic to any of the ingredients in COPEGUS.** The active ingredient in
723 COPEGUS is ribavirin. See the end of this Medication Guide for a list of all the
724 ingredients in COPEGUS.

725 **Tell your healthcare provider before starting treatment with COPEGUS in**
726 **combination with PEGASYS (see also the PEGASYS Medication Guide) if you have**
727 **any of the following medical conditions:**

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- 728 • **mental health problems, such as depression or anxiety:** COPEGUS and
729 PEGASYS combination therapy may make them worse. Tell your healthcare provider
730 if you are being treated or had treatment in the past for any mental problems,
731 including depression, thoughts of ending your life (suicidal thoughts) or a feeling of
732 loss of contact with reality, such as hearing voices or seeing things that are not there
733 (psychosis). Tell your healthcare provider if you take any medicines for these
734 problems.
- 735 • **high blood pressure, heart problems or have had a heart attack.** COPEGUS may
736 worsen heart problems such as high blood pressure, increased heart rate, and chest
737 pain. Tell your healthcare provider if you have or had a heart problem. Patients who
738 have had certain heart problems should not take COPEGUS.
- 739 • **blood disorders,** including anemia (low red blood cell count), thalassemia
740 (Mediterranean anemia) and sickle-cell anemia. COPEGUS can reduce the number of
741 red blood cells you have. This may make you feel dizzy or weak and could worsen
742 any heart problems you might have.
- 743 • **kidney problems.** If your kidneys do not work properly, you may have worse side
744 effects from COPEGUS treatment and require a lower dose.
- 745 • **liver problems** (other than hepatitis C virus infection).
- 746 • **organ transplant,** and you are taking medicine that keeps your body from rejecting
747 your transplant (suppresses your immune system).
- 748 • **thyroid disease.** COPEGUS and PEGASYS combination therapy may make your
749 thyroid disease worse or harder to treat. COPEGUS and PEGASYS treatment may be
750 stopped if you develop thyroid problems that cannot be controlled by medicine.
- 751 • **have or had drug or alcohol addiction or abuse.**
- 752 • **cancer.**
- 753 • **infection with hepatitis B virus.**
- 754 • **diabetes.** COPEGUS and PEGASYS combination therapy may make your diabetes
755 worse or harder to treat.
- 756 • **past interferon treatment for hepatitis C virus infection that did not work for**
757 **you.**
- 758 **Tell your healthcare provider about all the medicines you take,** including prescription
759 and non-prescription medicines, vitamins or herbal supplements. Some medicines can
760 cause serious side effects if taken while you also take COPEGUS. Some medicines may
761 affect how COPEGUS works or COPEGUS may affect how your other medicines work.
762 Be especially sure to tell your healthcare provider if you take any medicines to treat HIV,
763 or if you take azathioprine (Imuran®).
- 764 **For more information see the PEGASYS Medication Guide.**

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765 How should I take COPEGUS?

- 766 • Your healthcare provider will determine the right dose of COPEGUS based on your
767 weight.
- 768 • Take COPEGUS 1 time in the morning and 1 time at night (2 times a day). Take
769 COPEGUS the same 2 times each day.
- 770 • Take COPEGUS with food.
- 771 • It is very important to follow your dosing schedule and your healthcare provider's
772 instructions on how to take your medicines.
- 773 • Take COPEGUS for as long as it is prescribed, and do not take more than your
774 healthcare provider prescribes.
- 775 • If you miss a dose of COPEGUS and remember **the same day**, take the missed dose
776 as soon as you remember. If **the whole day has passed**, ask your healthcare provider
777 what to do. Do not take 2 doses at the same time.
- 778 • Your healthcare provider may adjust your dose of COPEGUS based on blood tests
779 that show your response to treatment and side effects you may have.
- 780 • **Females taking COPEGUS or female sexual partners of male patients taking**
781 **COPEGUS must have a pregnancy test:**
- 782 • before treatment begins
- 783 • every month during treatment
- 784 • for 6 months after treatment ends to make sure there is no pregnancy

785 It is also important not to use other ribavirin medicines without talking to your healthcare
786 provider. Please see the PEGASYS Medication Guide for the proper use of PEGASYS
787 injection.

788 What should I avoid while taking COPEGUS?

789 **Avoid the following during COPEGUS treatment:**

- 790 • **Do not get pregnant.** If you or your sexual partner get pregnant during treatment
791 with COPEGUS or in the 6 months after treatment ends, tell your healthcare provider
792 right away. (See “**What is the most important information I should know about**
793 **COPEGUS?**”.)
- 794 Talk with your healthcare provider about birth control methods and how to avoid
795 pregnancy. You must use extreme care to avoid pregnancy during and for 6 months
796 after treatment in female and male patients.
- 797 • **Do not take COPEGUS alone to treat your hepatitis C virus infection.**
798 COPEGUS should be used in combination with PEGASYS (peginterferon alfa-2a) to
799 treat chronic hepatitis C virus infections. (See “**What is the most important**
800 **information I should know about COPEGUS?**”.)
- 801 • **Do not breast feed.** COPEGUS may pass through your milk and may harm your
802 baby.
- 803 • **Do not drink alcohol**, including beer, wine, and liquor. This may make your liver
804 disease worse.

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805 • **Do not drive or operate machinery** if COPEGUS makes you feel tired, dizzy or
806 confused.

807 • **Do not take other medicines unless your healthcare provider knows about them.**
808 Take only medicines prescribed or approved by your healthcare provider. These
809 include prescription and non-prescription medicines, vitamins or herbal supplements.
810 Talk to your healthcare provider before starting any new medicine.

811 **What are the possible side effects of COPEGUS?**

812 **The most serious possible side effects of COPEGUS are:**

813 • **Harm to unborn children.** COPEGUS may cause birth defects or death of an unborn
814 child. (For more details, see “**What is the most important information I should**
815 **know about COPEGUS?**”.)

816 • **Anemia.** Anemia is a reduction in the number of red blood cells you have. Anemia
817 can be dangerous, especially if you have heart or breathing problems. Tell your
818 healthcare provider right away if you feel tired, have chest pain or shortness of breath.
819 These may be signs of low red blood cell counts.

820 • **Liver problems.** Some patients may develop worsening of liver function. Some of
821 the symptoms may include stomach bloating, confusion, brown urine, and yellow
822 eyes. Tell your healthcare provider immediately if any of these symptoms occur.

823 **Call your healthcare provider right away if you have any of the following symptoms.**
824 **They may be signs of a serious side effect of COPEGUS and PEGASYS treatment.**

825 • trouble breathing

826 • hives or swelling

827 • chest pain

828 • severe stomach pain or low back pain

829 • bloody diarrhea or bloody stools (bowel movements). These may look like black tar.

830 • bruising or unusual bleeding

831 • change in your vision

832 • high fever (temperature greater than 100.5°F)

833 • you have psoriasis (a skin disease) and it gets worse

834 • you become very depressed or think about suicide (ending your life)

835 • Skin rash can occur in patients taking PEGASYS. In some patients a rash can be
836 serious. If you develop a rash with fever, blisters, or sores in your mouth, nose or
837 eyes or conjunctivitis (red or inflamed eyes, like “pink eye”), stop using PEGASYS
838 and call your doctor right away

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840 **The most common side effects of COPEGUS are likely to be the same as for other**
841 **ribavirin products. These are:**

842 • feeling tired

843 • nausea and appetite loss

844 • rash and itching

845 • cough

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846 These are not all the possible side effects of COPEGUS treatment. For more information,
847 ask your doctor or pharmacist and see the PEGASYS Medication Guide. Call your doctor
848 for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-
849 1088. You may also report side effects to Genentech at 1-888-835-2555.

850 **What should I know about hepatitis C infection?**

851 Hepatitis C infection is a disease caused by a virus that infects the liver. Hepatitis C is
852 more serious for some people than others. Most people who get hepatitis C carry the virus
853 in their blood for the rest of their lives. Most of these people will have some liver
854 damage, but many do not feel sick from the disease. In some people, the liver becomes
855 badly damaged and scarred. This is called cirrhosis. Cirrhosis can cause the liver to stop
856 working. Some people may get liver cancer or liver failure from the hepatitis C virus.

857 Hepatitis C virus is spread from one person to another by contact with an infected
858 person's blood. You should talk to your healthcare provider about ways to prevent you
859 from infecting others.

860 **How should I store COPEGUS?**

861 Store COPEGUS tablets at room temperature (77°F).

862 Please refer to the PEGASYS Medication Guide for storage information about
863 PEGASYS injection.

864 **General information about the safe and effective use of COPEGUS**

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

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

872 **What are the ingredients in COPEGUS?**

873 Active Ingredient: ribavirin

874 Inactive Ingredients: The core of the tablet contains corn starch, magnesium stearate,
875 microcrystalline cellulose, pregelatinized starch, and sodium starch glycolate. The
876 coating of the tablet contains ethyl cellulose (200 mg tablet only), hydroxypropylmethyl
877 cellulose, red iron oxide, talc, titanium dioxide, triacetin, and yellow iron oxide.

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879 This Medication Guide has been approved by the US Food and Drug Administration.

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