

Fighting hepatitis C when you have HIV



PEGASSISTSM

Where patients matter



Roche

Pharmaceuticals

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Introduction

If you are reading this, you and your doctor have decided that hepatitis C (Hep C) treatment is right for you. You should know that 1 out of 3 Americans with HIV also has Hep C—so you are not alone.

This booklet will answer many of your questions about Hep C. Inside, there is information about:

- The medicines that help fight Hep C
- How to deal with the way your medication makes you feel (side effects)
- Ways to try to make your liver healthier

You may be upset to learn you have two viral diseases. However, two prescription medications are approved by the **FDA** to treat Hep C in patients who have clinically stable HIV: PEGASYS® (Peginterferon alfa-2a) with or without COPEGUS® (Ribavirin, USP). Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

Your doctor and nurse will support you during treatment, so follow their instructions. And, if you need help, reach out to them.



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

What medications are approved by the FDA for treating Hep C?

The FDA has approved *only* two drugs to treat Hep C in patients who also have clinically stable HIV.

- PEGASYS, also known as peginterferon alfa-2a
- COPEGUS, also known as ribavirin

PEGASYS + COPEGUS are usually taken together for Hep C treatment. Some patients may experience side effects. Please see pages 11-12 and 28-31 for Important Safety Information including side effects.

What are PEGASYS and COPEGUS?

PEGASYS is a long-acting interferon.

Interferon is a group of small proteins normally made by your body's cells when they come in contact with a **virus**. It works by trying to stop the virus from growing in number. PEGASYS is a medication similar to the interferon found in your body.

PEGASYS helps the body fight Hep C in two ways:

- First, it helps protect healthy cells against Hep C
- Second, it helps to stop the Hep C virus from growing in number

COPEGUS helps PEGASYS do its job. It's a man-made drug that helps to slow down the growth of the Hep C virus. It is usually taken for as long as you are taking PEGASYS.



Please see the glossary at the end of this booklet for definitions of key words.

How do I know if PEGASYS and COPEGUS are working?

Your doctor will most likely do **viral load** tests during treatment to make sure the medications are working. Your doctor will do a final viral load test 6 months after you finish your Hep C medication to see if the virus is undetectable. If it shows that the Hep C virus is undetectable, you have achieved an SVR (**sustained virologic response**). An SVR means you have responded to treatment and the medication was successful.

How does taking PEGASYS and COPEGUS affect my HIV?

Studies have shown that PEGASYS and COPEGUS do not affect HIV viral load. When patients were given these medications, their HIV viral loads did not go up during treatment.

What effect do PEGASYS and COPEGUS have on CD4+ cell counts?

As a person with HIV, you are probably well aware of your CD4+ cell count and understand how important it is to keep it as high as possible. You may even use it as a measure of your HIV control.

In studies, the CD4+ cell counts of some patients with HIV taking PEGASYS and COPEGUS went down temporarily. But after treatment ended, it went back up to the level it was before they started taking these medications. Your doctor will continue to monitor your CD4+ cell counts during therapy.

Remember, any drop in CD4+ cell count shouldn't last after treatment has ended and helping your liver is more important than the small amount of time your CD4+ cell count may change.



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

What HIV medications should I avoid when I am on Hep C medication?

You should not take didanosine with COPEGUS. Talk to your doctor about other medications you can take instead.

Your doctor will watch you to make sure you are not having problems taking other HIV drugs with PEGASYS and COPEGUS.

How do I take PEGASYS and COPEGUS?

PEGASYS comes in a prefilled syringe that is ready for you to inject yourself. COPEGUS comes in pills that you take by mouth.

How long do I take PEGASYS and COPEGUS?

You should follow your doctor's instructions. The recommended time period for treatment is 48 weeks, no matter what strain (**genotype**) of Hep C you have.

What dose of PEGASYS do I use?

You should follow your doctor's instructions. The recommended dose of PEGASYS is 180 micrograms once a week. If you are having a problem, your doctor might reduce the dose for a while to either 135 micrograms or 90 micrograms. Both of these doses are marked on the prefilled syringe.

What dose of COPEGUS do I use?

You should follow your doctor's instructions. The recommended dose of COPEGUS is 800 milligrams each day. Again, if there is a problem, your doctor might reduce the dose. Always follow your doctor's instructions.



Please see the glossary at the end of this booklet for definitions of key words.

How do I take PEGASYS?

You will give yourself an injection of PEGASYS once each week. It comes already mixed as a liquid in a prefilled syringe. You should take PEGASYS every week on the same day. You will give the injection under your skin in either your stomach or your thigh. Give your skin a rest by changing your injection site each time. **(See the enclosed medication guide for full instructions on how to inject PEGASYS. If you have any questions, call your doctor.)**

How do I take COPEGUS?

You will take COPEGUS twice a day; two pills in the morning and two pills at night and usually with food. **(See the enclosed medication guide for full instructions on how to take COPEGUS. If you have any questions, call your doctor.)**

What happens if I miss a dose of PEGASYS or COPEGUS?

Taking every dose of both PEGASYS and COPEGUS will give you your best chance for fighting Hep C.

If you are 1 or 2 days late in taking PEGASYS, just give yourself the injection when you remember. Then take your next dose of PEGASYS on your regular day.

If you are more than 2 days late, call your doctor and ask what to do.

If you miss the time you usually take COPEGUS, take your tablets when you remember. Do not double your next dose of COPEGUS. Also, do not take both doses too close together. **(See the enclosed medication guide for full instructions on how to take COPEGUS. If you have any questions, call your doctor.)**



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

How do I store PEGASYS and COPEGUS?

You need to store PEGASYS in the refrigerator at a temperature of 36° to 46°. Do not freeze or shake PEGASYS. Make sure to keep PEGASYS away from light. Each syringe is for one use only. Throw out any leftover PEGASYS if your doctor has told you to take less than a full dose.

Store COPEGUS at room temperature.

How do I dispose of the PEGASYS Prefilled Syringe?

Every state has different laws about medical waste. You need to find out the laws in your state and follow them.

To protect yourself and others from needle pricks, it is very important that you remember to lock the needleguard after injection. And, never reuse either the syringe or the needle.

You should throw them into a sharps container from your drug store. This container should not be glass or clear plastic. Do not throw used syringes or needles in the regular garbage. Ask your doctor and pharmacist what to do with the prefilled syringe when you are done with it.

What if I need to travel with PEGASYS?

If you travel, you need to

- Keep PEGASYS cold
- Keep it in the original package so others will know that PEGASYS is your medicine
- If you visit a different time zone, you will have to change the time of your dose to keep with your same schedule
- Pack extra doses in case you get delayed
- Consult your local carrier for specific rules

Please see the glossary at the end of this booklet for definitions of key words.



Where patients matter



What if I am pregnant or thinking about having a baby?

Women who are pregnant and the male partners of women who are pregnant cannot take COPEGUS. This is because COPEGUS may cause major birth defects or death of the unborn baby. You (or your female partner, if you are a man) may also miscarry.

If you are a woman who can get pregnant, you must take a pregnancy test before you take COPEGUS. If this test is positive, you cannot start taking your medication.

If you are a man who has a female partner who can get pregnant, she must take a pregnancy test before you take COPEGUS.

During Hep C treatment and for 6 months after you stop taking your medication, you must:

- Use 2 forms of birth control
- Get a pregnancy test every month

If you or your female partner gets pregnant during treatment or within 6 months after treatment stops, contact your doctor right away. Please call the Ribavirin Pregnancy Registry at 1-800-593-2214.

After I start treatment, what can I expect?

In a little less than a year, you'll be done taking PEGASYS and COPEGUS. But right now, knowing what to expect can help you be prepared. And being prepared may help your treatment be successful.

Do not feel like you are alone. Your family and friends can give you support and help you when you need it. Let the people around you know what to expect before you start taking your medications. This is very important because you may feel ill, yet still look okay to those around you. Your doctor or nurse may be able to help you in talking to your loved ones.



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

How often do I need to see my doctor after starting medication?

You and your doctor can decide when you should have follow-up visits. It is very important that you keep all of your appointments with your doctor.

What laboratory tests will my doctor order during treatment?

Your doctor will order regular tests to check your

- Hep C viral load to see if the medications are working
- Red and white blood-cell counts
- Liver function and other blood counts, like uric acid
- Thyroid function every 12 weeks
- A pregnancy test for you (if you are a woman) or your female partner (if you are a man)

What side effects might I experience while taking PEGASYS and COPEGUS?

Although there are side effects that may happen from taking Hep C medicines, in studies, 3 out of 4 patients taking Hep C medicines were able to finish their treatment. Your doctor can give you more information about side effects and how to deal with them.

The most common side effects from PEGASYS and COPEGUS treatment are tiredness, sleeplessness, nausea (upset stomach), loss of appetite (not feeling hungry), flu-like symptoms (like chills and fever), depression, hair loss, skin problems (like itchiness and dryness), anemia (low red-blood-cell count, which can cause problems like feeling dizzy or tired) and neutropenia (a type of low white-blood-cell count, which can make it harder to fight infection).

Other more serious side effects that happen less often include risks to pregnancies, autoimmune problems (like psoriasis and thyroid problems), heart problems (like chest pain and, rarely, heart attack) and liver problems (rarely, liver function gets worse).

Please see the glossary at the end of this booklet for definitions of key words.



Side effects (continued)

You may have heard that these side effects are difficult to handle. You can manage some side effects with simple lifestyle changes or over-the-counter medications. Other times, your doctor may prescribe medicines to help you with side effects. Sometimes, your doctor may reduce the dose of one of your drugs for a while. Once the side effect improves, you may be able to go back to the full dose.

Keep in mind:

- Not everyone experiences the same amount of side effects
- Your doctor may be able to help you
- Contact your doctor if you have questions or concerns about these or any other side effects
- Keep all your appointments with your doctor, who has experience in handling the side effects of Hep C medications

How important is it that I stay on treatment?

Staying on treatment is very important. If you stop taking your medicines, the Hep C virus has a chance to start multiplying all over again. If you don't take your medicines as directed, PEGASYS and COPEGUS might not work.

How do I cope with side effects?

In addition to the advice given by your doctor, this section will give you tips about how to deal with these common side effects:

- Tiredness and sleeplessness
- Nausea and loss of appetite
- Flu-like symptoms
- Depression
- Hair loss
- Skin problems, including injection-site reactions
- Anemia



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

Coping with side effects

Very often these side effects can be controlled with the tips in this section. If you have trouble with any other side effects, talk to your doctor.

Managing tiredness and sleeplessness

Tiredness is the most commonly reported side effect of patients taking PEGASYS. The feeling of tiredness occurs most often at the beginning of treatment and lessens with time. Other common symptoms are difficulty falling asleep or trouble staying asleep. Lack of sleep can make patients more tired.

Tips for managing tiredness:

- Take PEGASYS at bedtime
- Drink plenty of fluids. Drinking more may help you feel less tired
- Maintain healthy overall nutrition. Talk with your doctor about taking vitamins and/or protein shakes, bars, etc
- Do aerobic exercise, such as walking
- Rest often and take short naps
- Schedule more demanding activities when you have the most energy
- Do things that are relaxing, such as watching movies or reading
- Shorten your work schedule
- Let friends and family help you
- Try stress reduction and relaxation techniques



Please see the glossary at the end of this booklet for definitions of key words.



Coping with side effects (continued)

Tips for managing sleeplessness:

- Exercise during the day, but don't exercise within 4 hours of bedtime
- Limit daytime naps
- Take warm baths, read or listen to soothing music before bedtime
- Talk with your doctor about prescription and nonprescription sleep aids
- Keep a journal. It may help you see ways to make changes, like limiting daytime naps
- Limit caffeine and alcohol
- Maintain a regular sleep schedule. Sleep only when drowsy
- Try relaxation techniques, like meditating
- Reduce noise at bedtime
- Limit drinks and avoid big meals close to bedtime

Managing nausea and loss of appetite

Many patients taking PEGASYS get some stomach problems. These problems range from nausea to diarrhea to abdominal cramps and loss of appetite. Not feeling hungry, even for your favorite foods, is one of the ways treatment can lead to weight loss. These problems tend to occur during the first month of treatment and lessen with time. However, it's important to watch changes in your weight and talk to your doctor about any stomach problems.

Tips to relieve nausea:

- Eat small meals often
- Be sure meals are lukewarm or cold in temperature. Food that is hot in temperature can upset your stomach
- Try to eat healthy foods. Avoid greasy or spicy foods or foods that have strong smells, such as heavily seasoned foods that can upset your stomach
- Snack on salty foods such as pretzels, peanut butter or crackers
- If you usually feel sick in the morning, keep crackers beside your bed. Before you get out of bed, sit up and eat a few crackers
- Try over-the-counter antacid medications. Ask your doctor about prescription medications that help prevent nausea
- After eating, do not lie down. Sit up or put pillows under your head and upper body
- Distract yourself by listening to music, reading, relaxing your muscles or imagining that you are in a place that is pleasant and comfortable
- Drink flat soda or eat something containing natural ginger, such as ginger ale or ginger snaps
- Keep active. Include aerobic exercise, like brisk walking, running or bike riding in your daily routine



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

Please see the glossary at the end of this booklet for definitions of key words.



Where patients matter

Coping with side effects (continued)

Tips to help loss of appetite:

- Eat a wide variety of foods from all the food groups. Choose different textures and colors: for example, colorful fruits and vegetables, whole grains, lean meats, cooked cereal, crunchy nuts
- Try to prepare and eat meals with family and/or friends
- Include meal-replacement drinks or bars as a part of your daily diet
- Make sure you are eating enough protein throughout the day
- Consider adding protein powder to foods and beverages
- Avoid carbonated beverages and foods that cause gas, such as broccoli or cabbage
- Eat what you want when you feel hungry or eat a lot of small meals (even if not hungry)
- Add mild spices to food to make meals taste better
- Avoid eating hot food. Eat food chilled or at room temperature
- Eat nutritious foods that are high in calories, such as peanut butter and cheese
- Do mild exercise, like walking, right before meals
- Talk with your doctor if you lose more than 2 pounds per week. You may need a prescription medication to make you hungry



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

Managing flu-like symptoms

Almost all Hep C patients have flu-like symptoms, such as muscle aches, joint pains, headache, chills and fever. These symptoms can be difficult to deal with, but there are ways to cope with them. Flu-like symptoms usually occur within 2 to 24 hours after PEGASYS injection. They tend to be at their worst at the beginning of treatment and lessen over time.

Tips for managing flu-like symptoms:

- Drink plenty of water each day. To figure out how many ounces you should drink each day:
 - Divide your weight by 2
 - Example: if you weigh 160 pounds, you should drink 80 ounces of water each day, or about ten 8-ounce glasses
- Inject PEGASYS right before bedtime so you can sleep through any flu-like symptoms
- Use extra blankets and clothes when you have the chills
- Use ice or gel packs for fevers, headaches and other aches and pains
- Take PEGASYS on a day that doesn't get in the way of your daily activities or work
- You can take an over-the-counter pain reliever 30 minutes prior to an interferon injection, but talk with your doctor first
- Avoid loud noises, bright lights, alcohol, caffeine and foods with tyramine (such as cheese and chocolate). This may help with headaches



Please see the glossary at the end of this booklet for definitions of key words.



Coping with side effects (continued)

Managing depression

Some people experience **depression** as a result of their Hep C treatment. Usually, patients begin feeling depressed after the 4th week of treatment.

Depression is very serious. If you have symptoms of depression, talk with your doctor right away.

Symptoms of depression:

- Depressed mood
- Loss of energy
- Feeling tired
- Lack of interest in your usual activities
- Trouble concentrating
- Changes in sleep patterns, such as difficulty sleeping
- Major weight loss in a short period of time
- Loss of appetite
- Crying for no reason
- Feelings of hopelessness or extreme sadness
- Thoughts of suicide or killing the people around you
- Major mood swings
- Rage or grouchiness

Ideas for coping with depression:

- If you have symptoms of depression, talk with your doctor right away. Depression can be treated
- Tell your doctor if you've ever been treated for depression or if any of your relatives have depression
- Keep a diary of any bad thoughts or feelings that are affecting your moods. This will help you be aware of how you're feeling on a daily basis
- Maintain regular routines in your life. For example, eat meals at the same time every day and go to sleep at the same time every night
- Do things that relieve stress. For example, get regular exercise, take time to relax or meditate
- Avoid drinking too much coffee or eating too much sugar, which can make you feel stressed
- Join a local support group to meet other people with HIV and Hep C
- Talk about your feelings with a family member or close friend. They can be a great source of support
- Take care of your body: eat healthy meals, drink plenty of water and get enough sleep
- Listen to those around you for clues that you may need to get help (moods of crankiness, grouchiness, nastiness)
- If you are taking medication for depression, don't skip a dose



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

Please see the glossary at the end of this booklet for definitions of key words.



Where patients matter

Coping with side effects (continued)

Managing hair loss

Many patients taking PEGASYS have some hair loss. This is usually mild. You might even be the only one who notices it. Hair loss/hair changes occur more often after 3 or 4 months of therapy. Hair changes can range from slight hair loss to thinning hair to changes in hair texture. Hair loss during treatment doesn't usually last.

Tips for managing hair loss:

- Do not comb or brush your hair too much. When you do, use a wide-toothed comb or soft brush
- Wash hair less often and use a cream rinse
- During treatment, do not perm or color your hair
- Don't use hair products that pull hair, like clips and bands
- Use less hair gel, spray and mousse. Avoid alcohol-based products, which can be drying
- Use a low-pressure showerhead
- Limit blow-drying or use of straightening irons
- Think about getting a shorter hairstyle
- Wear a scarf, hat or wig
- Use a mild shampoo. Ask a hair stylist for a good product
- Do not use prescription hair-loss medication—it will not work for this kind of hair loss



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

Managing skin problems

Mild skin problems, such as itchiness, redness, dryness or sores, may occur during treatment. Some people may get mild reactions at the site of their injections. Hep C medication can also make pre-existing eczema flare up. Your immune system response may be lowered, making skin infections possible. These skin problems are usually not serious, and they often go away on their own.

Tips to help prevent skin problems at the injection site:

- Follow your doctor's instructions for injecting PEGASYS
- Gently roll the PEGASYS syringe in your hands for a minute to warm the medicine
- Give your skin a rest by changing injection-site areas each time
- Check your injection site for signs of redness, swelling or pain. Call your doctor right away if you have any of these signs
- Apply cool or warm compresses to the area before or after your injection
- Limit sun exposure at the injection site. Use sunscreen, regardless of skin color
- Apply moisturizing creams to the area. Avoid alcohol-based skin creams. Speak with your doctor before using hydrocortisone cream or anti-itch medications, and use only as directed



Please see the glossary at the end of this booklet for definitions of key words.



Coping with side effects (continued)

Ideas for dealing with skin problems:

- Keep your skin moisturized; the best time to moisturize is right after you shower
- Apply a thin layer of petroleum jelly to dry, itchy areas
- Take lukewarm baths. Add oil to the water at the end of the bath to moisturize your skin. Add oatmeal to relieve itching
- Rub or press itchy areas rather than scratching. Use an ice cube to scratch itchy areas, rather than your fingers
- Drink plenty of noncaffeinated drinks
- Eat well. Talk with your doctor about taking vitamins and/or protein shakes, bars, etc
- Use mild soaps and mild laundry detergents
- Ask your doctor about medicines to relieve pain or prevent allergies that may be causing your skin problems

Managing anemia

Your doctor will watch your blood test results to make sure that you do not become anemic (a drop in your red blood cells to below normal levels). Anemia can make heart problems worse. People with heart problems must be very careful about anemia.

You will get a blood test for anemia before treatment. Your doctor will continue to do blood tests throughout treatment. It is very important that you follow your doctor's instructions and keep all your appointments for blood work. Symptoms of anemia include tiredness, dizziness, paleness, shortness of breath and feeling cold.

Tips for managing anemia:

- Keep all appointments for blood work
- If you have trouble breathing or have chest pain, call your doctor right away
- Discuss any signs or symptoms of anemia with your doctor
- Follow any instructions for dose reductions if necessary



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

Please see the glossary at the end of this booklet for definitions of key words.



Where patients matter

PegassistSM—Hep C support whenever you need it

As you start your treatment, you are joining thousands of other people with HIV who are taking steps to help stop the Hep C virus from damaging their livers. The *first and only* treatment available to fight the Hep C virus in people with both clinically stable HIV and Hep C is PEGASYS and COPEGUS.

To support you in your fight against Hep C, we have developed Pegassist—a patient support program designed to give you answers, help and support when you need it most. All Pegassist services and materials are free, and you do not need to register or enroll.

Call us...we're here for you

- Speak to a registered nurse around the clock for answers to questions about Hep C and your treatment (available in 150 languages)
 - Enroll in our nursing support program and a nurse will make regular appointments to call you during treatment
- Order a *Getting Started* patient kit, which includes:
 - A video on how to inject yourself
 - Booklets that have more information on Hep C, PEGASYS and COPEGUS treatment and the Pegassist support program
 - Other tools to help you get through your treatment



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

Or go online anytime

- Get information about Hep C and your medications
- Use our Web tools to help you follow your progress
- Read our newsletter to find out about Hep C events in your area



To find out more about these services, call 1-877-PEGASYS (1-877-734-2797) or just log on to www.pegassist.com or www.pegasys.com

This booklet is designed to provide general information to patients. You should always seek the advice of your doctor if you have any condition that may require medical treatment.

Please see the glossary at the end of this booklet for definitions of key words.



Other sources of information

HIV and Hepatitis.com

P.O. Box 14288
San Francisco, CA 94114

National AIDS Treatment Advocacy Project (NATAP)

580 Broadway, Suite 1010
New York, NY 10012
(888) 26-NATAP (266-2827)
(212) 219-0106
<http://www.natap.org>

National Hepatitis C Coalition, Inc.

P.O. Box 5058
Hemet, CA 92544
National HepLine: (951) 658-4414
<http://www.nationalhepatitis-c.org>

American Liver Foundation

75 Maiden Lane, Suite 603
New York, NY 10038
(800) GO-LIVER (465-4837)
(888) 4-HEP-ABC (443-7222)
<http://www.liverfoundation.org>

Centers for Disease Control and Prevention (CDC)

1600 Clifton Road
Atlanta, GA 30333
(888) 4-HEP-CDC (443-7232)
<http://www.cdc.gov/hepatitis>

Hepatitis Foundation International

504 Blick Drive
Silver Spring, MD 20904-2901
(800) 891-0707
(301) 622-4200
<http://www.hepfi.org>

Visionary Health Concepts

<http://www.freehivinfor.com>
ed@vhconcepts.com
(fax) (800) 407-2505

Glossary

Depression: A state of mind in which there may be problems focusing, not being interested in things you used to like, feeling guilty or hopeless, or even thoughts about death or suicide

FDA (Food and Drug Administration): Government agency responsible for assuring the safety and effectiveness of a range of products

Genotype: Genetic makeup, or strain of a virus

Interferon: A protein produced by the body that fights an intruder, such as a virus, by stopping it from multiplying

Sustained virologic response (SVR): The virus is undetectable in the blood for 6 or more months after the end of treatment

Viral load: How much virus is in your body

Virus: A tiny infectious agent that causes disease



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.



Important Safety Information

What is PEGASYS?

PEGASYS is a medication used to treat some adults who have hepatitis C and signs of liver damage. PEGASYS works to reduce the amount of virus in your blood, helping your body fight the virus.

PEGASYS (Peginterferon alfa-2a), like other alpha interferons, can cause fatal or make life-threatening problems worse (like mental, immune system, heart, liver, lung, intestinal and infections). Your doctor should monitor you during regular visits. If you show signs or symptoms of these conditions, your doctor may stop your medication. In most patients, these conditions get better after you stop taking PEGASYS (see medication guide for more information and warnings).

What is COPEGUS?

COPEGUS is a medication that works by slowing down the growth of the virus. COPEGUS should be taken with PEGASYS to fight the virus. **Do not take COPEGUS by itself.**

COPEGUS (Ribavirin, USP) can be extremely harmful and cause birth defects in an unborn baby. Female patients and the female partners of male patients should avoid getting pregnant. Ribavirin is known to cause anemia (low red blood cells), which can make heart disease worse. Also, ribavirin can harm your DNA and possibly cause cancer (see medication guide for more information and warnings).



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

Who should not take PEGASYS and COPEGUS?

Do not take PEGASYS alone or with COPEGUS if:

- You are pregnant or your partner is pregnant
- You or your partner plans to get pregnant during therapy or within 6 months after treatment ends
- You are breastfeeding
- You have hepatitis caused by your immune system (autoimmune hepatitis)
- You have unstable liver disease before or during treatment
- You are allergic to alpha interferons or any of the ingredients in PEGASYS and COPEGUS
- You have HIV with unstable or advanced liver disease
- You have abnormal red blood cells (caused by conditions like sickle-cell anemia or thalassemia major)

Please turn the page for additional safety information.

Important Safety Information (continued)

What if I am pregnant or thinking about having a baby?

If you are a woman who could get pregnant, you must take pregnancy tests before, during and for 6 months after treatment ends to make sure you are not pregnant.

During treatment and for 6 months after treatment, female and male patients must:

- Use two forms of birth control (one being a condom with spermicide)
- Tell your doctor right away if you or your partner becomes pregnant. You or your doctor should also call the Ribavirin Pregnancy Registry at 1-800-593-2214

What medications should I avoid when I am taking PEGASYS and COPEGUS?

You should not take didanosine with COPEGUS. Talk to your doctor about all medications that you are taking.



Please see Important Safety Information at the end of this booklet and enclosed patient medication guides for PEGASYS and COPEGUS.

What are the possible side effects?

The most common side effects of PEGASYS and COPEGUS are:

- Flu-like symptoms (including fever, chills, muscle aches, joint pain, headaches)
- Tiredness
- Upset stomach (like nausea, taste changes, diarrhea)
- Blood sugar problems (may lead to diabetes)
- Skin problems (like rash, dry or itchy skin and redness and swelling at injection site)
- Hair loss (temporary)
- Trouble sleeping

The most serious side effects of PEGASYS and COPEGUS are:

- Risks to pregnancies
- Mental health problems (such as irritability, depression, anxiety, aggressiveness, trouble with drug addiction or overdose, feeling suicidal, including thoughts about suicide and suicide attempts)
- Blood problems (like a drop in blood cells leading to increased risk for infections, bleeding and/or heart or circulatory problems)
- Infections (which sometimes cause death)
- Lung problems (like trouble breathing, pneumonia)
- Eye problems (like blurred vision, loss of vision)
- Autoimmune problems (such as psoriasis, thyroid problems)
- Heart problems (including chest pain and, rarely, a heart attack)
- Liver problems (rarely, liver function worsens)

Tell your doctor immediately if you think you or your partner may be pregnant or if any of these symptoms occur.



Where patients matter



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(Peginterferon alfa-2a) FOR INJECTION

COPEGUS[®]
(Ribavirin, USP) 200 MG TABLETS

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