

Medication Guide
PEGASYS® (PEG-ah-sis)
(peginterferon alfa-2a)
Solution for Subcutaneous Injection

Read this Medication Guide before you start taking PEGASYS, 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.

If you are taking PEGASYS with or without other medicines for treatment of hepatitis C, also read the Medication Guides or Patient Information for all the relevant medicines.

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

1. **Ribavirin in combination with PEGASYS may cause birth defects or death of your unborn baby.** If you are pregnant or your sexual partner is pregnant or plans to become pregnant, do not take PEGASYS/ribavirin combination therapy. You or your sexual partner should not become pregnant while you take PEGASYS/ ribavirin combination therapy and for 6 months after treatment is over. You must use 2 forms of birth control one of which should be a condom with spermicide when you take PEGASYS/ ribavirin combination therapy and for the 6 months after treatment.
 - Females must have a pregnancy test before starting PEGASYS/ ribavirin combination therapy, every month while being treated, and every month for the 6 months after treatment with PEGASYS/ ribavirin combination therapy.
 - **If you or your female sexual partner becomes pregnant** while taking PEGASYS/ ribavirin or within 6 months after you stop taking PEGASYS/ ribavirin, 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 PEGASYS/ ribavirin while she is pregnant.
2. **Mental health problems and suicide.** PEGASYS therapy may cause you to develop mood or behavioral problems, including:
 - irritability (getting upset easily)
 - depression (feeling low, feeling bad about yourself or feeling hopeless), and anxiety
 - aggressive behavior
 - former drug addicts may fall back into drug addiction or overdose
 - thoughts of hurting yourself or others, or suicide
3. **Heart problems.** Some people who take PEGASYS may get heart problems, including:
 - high blood pressure
 - fast heart rate or abnormal heart beat
 - chest pain

- heart attacks
4. **Stroke or symptoms of a stroke.** Symptoms may include weakness, loss of coordination, and numbness. Stroke or symptoms of a stroke may happen in people who have some risk factors or no known risk factors for a stroke.
 5. **New or worsening autoimmune problems.** Some people taking PEGASYS develop autoimmune problems (a condition where the body's immune cells attack other cells or organs in the body), such as rheumatoid arthritis, systemic lupus erythematosus, and psoriasis. In some people who already have an autoimmune problem, it may get worse during your treatment with PEGASYS.
 6. **Infections.** Some people who take PEGASYS may get an infection. Symptoms may include:
 - fever
 - chills
 - burning and painful urination
 - urinating often
 - coughing up yellow or pink mucus (phlegm)

Before taking PEGASYS, tell your healthcare provider if you:

- have or ever had any problems with your heart, including heart attack or have high blood pressure
- are being treated for a mental illness or had treatment in the past for any mental illness, including depression and suicidal behavior
- have any kind of autoimmune disease (where the body's immune system attacks the body's own cells), such as psoriasis, systemic lupus erythematosus, rheumatoid arthritis
- have or ever had low blood cell counts
- have or had blood disorders (bleeding problems or a blood clot, thalassemia major or sickle-cell anemia)
- have ever been addicted to drugs or alcohol

Call your healthcare provider right away if you get any of these problems while taking PEGASYS:

- new or worse mental health problems, such as thoughts of hurting yourself or others, or suicide
- trouble breathing or chest pain
- any new weakness, loss of coordination, or numbness
- symptoms of infection including: fever, chills, burning or pain with urination, urinating often, tiredness, or coughing up yellow or pink mucus (phlegm)

During treatment with PEGASYS you will need to see your healthcare provider regularly and have blood tests to make sure that your treatment is working and to check for side effects.

PEGASYS can cause serious side effects. Some of these side effects may cause death. Tell your healthcare provider right away if you have any of these symptoms while taking

PEGASYS. Other serious side effects are listed in “What are the possible side effects of PEGASYS?”

What is PEGASYS?

PEGASYS is a prescription medicine that is:

- used alone or with other hepatitis C medicines to treat adults and children 5 years and older who have chronic (lasting a long time) hepatitis C infection and certain types of liver problems, and who have not taken alpha interferon
- used with other hepatitis C medicines to treat adults with chronic hepatitis C and certain types of liver problems
- used if you have chronic hepatitis C infection, and you should not take PEGASYS by itself unless you are not able to take other hepatitis C medicines
- used to treat adults with chronic hepatitis B virus who show signs that the virus is damaging the liver

It is not known if PEGASYS is safe and will work in children under 5 years of age.

Who should not take PEGASYS?

Do not take PEGASYS if you:

- have certain other liver problems
- have certain types of hepatitis caused by your immune system attacking your liver (autoimmune hepatitis)
- have had a serious allergic reaction to another alpha interferon medicine or to any of the ingredients in PEGASYS. Symptoms of a serious allergic reaction to alpha-interferon may include: itching, swelling of your face, tongue, throat, trouble breathing, feeling dizzy or faint, and chest pain. See the end of this Medication Guide for a list of the ingredients in PEGASYS.

Do not take PEGASYS in combination with ribavirin if you:

- are pregnant, or planning to get pregnant during treatment or during the 6 months after treatment
- are a male patient with a female sexual partner who is pregnant or plans to become pregnant at any time while you are being treated with ribavirin or during the 6 months after your treatment has ended

Talk to your healthcare provider before taking PEGASYS if you have any of these conditions.

Do not give PEGASYS to a baby under 1 year of age. PEGASYS contains benzyl alcohol. Benzyl alcohol can cause nervous system problems and other problems which may lead to death.

What should I tell my healthcare provider before taking PEGASYS?

Before taking PEGASYS, see “What is the most important information I should know about PEGASYS?” and tell your healthcare provider if you have:

- liver problems (other than hepatitis B or C) or had lung problems

- thyroid problems
- diabetes
- colitis (inflammation of your intestine)
- cancer
- hepatitis B or C infection
- HIV infection (the virus that causes AIDS)
- kidney problems
- high blood triglyceride levels (fat in your blood)
- an organ transplant
- any other medical conditions
- are pregnant or plan to become pregnant. It is not known if PEGASYS will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with PEGASYS.
- are breastfeeding or plan to breast-feed. It is not known if PEGASYS passes into your breast milk. You and your healthcare provider should decide if you will use PEGASYS or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. PEGASYS and certain other medicines may affect each other and cause side effects.

- **Especially tell your healthcare provider if you take:**
- the anti-hepatitis B medicine telbivudine (Tyzeka)
- theophylline (Theo-24, Elixophyllin, Uniphyl, Theolair). Your healthcare provider may need to monitor the amount of theophylline in your body and make changes to your theophylline dose.
- any anti-HIV medicines
- methadone hydrochloride (Methadose, Dolophine hydrochloride)

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

How should I take PEGASYS?

- PEGASYS is given by injection under the skin (subcutaneous injection).
- Your healthcare provider will decide on your dose of PEGASYS and when you will take it. PEGASYS is usually injected one time each week. For children 5 years of age and older, your healthcare provider will prescribe the dose of PEGASYS based on height and weight.
- If your healthcare provider decides that you can inject PEGASYS for your condition, inject it exactly as prescribed.
- Your healthcare provider may change your dose of PEGASYS if needed. Do not change your dose unless your healthcare provider tells you to change it.
- Do not switch to another brand of interferon without talking to your healthcare provider
- Take your prescribed dose of PEGASYS 1 time each week, on the same day of each week and at approximately the same time.

- Do not take more than your prescribed dose.
- If you miss your dose:
 - If you remember **within 2 days** of when you should have taken PEGASYS, give yourself an injection of PEGASYS as soon as you remember. Take your next dose on the day you would usually take it.
 - If **more than 2 days** have passed, ask your healthcare provider what you should do.
- PEGASYS comes as a liquid:
 - in a single use vial
 - in a prefilled syringe
 - in an autoinjector

Your healthcare provider will decide which one is best for you.

- Your healthcare provider should show you how to **prepare and measure** your dose of PEGASYS if you will be using **single use vials or prefilled syringes** to inject PEGASYS.
- Your healthcare provider should show you how to **inject** yourself **before** you use a PEGASYS single use vial, prefilled syringe, or autoinjector for the first time.
- See the Instructions for Use that comes with your PEGASYS for detailed instructions about preparing and injecting a dose of PEGASYS.
- Do not re-use PEGASYS single use vials, prefilled syringes, autoinjectors, and needles.
- If you take more than the prescribed amount of PEGASYS, call your healthcare provider right away. Your healthcare provider may want to examine you and do blood tests.
- During treatment with PEGASYS you will need to see your healthcare provider regularly and have blood tests to make sure that your treatment is working and to check for side effects.
- It is not known whether PEGASYS will prevent an infected person from spreading the hepatitis B or C virus to another person.

What should I avoid while taking PEGASYS, or PEGASYS with ribavirin?

- If you are pregnant do not start taking or continue taking PEGASYS alone or in combination with ribavirin. (See “**What is the most important information I should know about PEGASYS?**”). Ribavirin in combination with PEGASYS may cause birth defects or death of your unborn baby.
- Avoid becoming pregnant while taking PEGASYS, alone or in combination with ribavirin. PEGASYS, alone or in combination with ribavirin, may harm your unborn child (death or serious birth defects) or cause you to lose your baby (miscarry). (See “**What is the most important information I should know about PEGASYS?**”)
- Do not breastfeed your baby while on PEGASYS, alone or in combination with ribavirin.
- Do not drink alcohol, including beer, wine and liquor. This may make your liver disease worse.
- Do not take other medicines. Take only medicines prescribed or approved by your healthcare provider. These include prescription and non-prescription medicines and herbal supplements.

What are the possible side effects of PEGASYS?

PEGASYS can cause serious side effects including:

- See “**What is the most important information I should know about PEGASYS?**”
- **Blood problems.** PEGASYS can affect your bone marrow and cause low red blood cell, low white blood cell and platelet counts. In some people, these blood counts may fall to dangerously low levels. If your blood cell counts become very low, you can get anemia, infections or have problems with bleeding and bruising.
- **Thyroid problems.** Some people develop changes in the function of their thyroid. Symptoms of thyroid changes include feeling cold or hot all the time, a change in your weight, and changes to your skin, trouble concentrating.
- **Blood sugar problems.** Some people may develop high blood sugar or diabetes. If you have high blood sugar or diabetes before starting PEGASYS, talk to your healthcare provider before you take PEGASYS. If you develop high blood sugar or diabetes while taking PEGASYS, your healthcare provider may tell you to stop PEGASYS and prescribe a different medicine for you. Symptoms of high blood sugar or diabetes may include:
 - increased thirst
 - tiredness
 - urinating more often than normal
 - increased appetite
 - weight loss
 - your breath smells like fruit
- **Serious eye problems.** PEGASYS may cause eye problems that may lead to vision loss or blindness. You should have an eye exam before you start taking PEGASYS. If you have eye problems or have had them in the past, you may need eye exams while taking PEGASYS. Tell your healthcare provider or eye doctor right away if you have any vision changes while taking PEGASYS.
- **Serious liver problems, worsening of liver problems including liver failure and death. Symptoms may include:**
 - nausea
 - loss of appetite
 - tiredness
 - diarrhea
 - yellowing of your skin or the white part of your eyes
 - bleeding more easily than normal
 - swelling of your stomach area (abdomen)
 - confusion
 - sleepiness
 - you cannot be awakened (coma)
- **Lung problems including:**

- trouble breathing
- pneumonia
- inflammation of lung tissue
- new or worse high blood pressure of the lungs (pulmonary hypertension). This can be severe and may lead to death.

You may need to have a chest X-ray or other tests if you develop fever, cough, shortness of breath or other symptoms of a lung problem during treatment with PEGASYS.

- **Inflammation of your pancreas (pancreatitis).** Symptoms of inflammation of your pancreas (pancreatitis) may include:
 - severe stomach (abdomen) pain
 - severe back pain
 - nausea
 - vomiting
 - fever
- **Inflammation of your intestines (colitis).** Symptoms of inflammation of your intestines (colitis) may include:
 - severe stomach area (abdomen) pain
 - bloody diarrhea or bloody bowel movements
- **Serious allergic reactions and skin reactions.** Symptoms may include:
 - itching
 - swelling of your face, eyes, lips, tongue, or throat
 - trouble breathing
 - anxiousness
 - chest pain
 - feeling faint
 - skin rash, hives, sores in your mouth, or your skin blisters and peels
- **Effect on growth in children.** Children can experience a delay in weight gain and height increase while being treated with PEGASYS. Catch-up in growth happens after treatment stops, but some children may not reach the height that they were expected to have before treatment. Talk to your healthcare provider if you are concerned about your child's growth during treatment with PEGASYS.
- **Nerve problems.** People who take PEGASYS or other alfa interferon products with telbivudine (Tyzeka) for hepatitis B can develop nerve problems such as continuing numbness, tingling, or burning sensation in the arms or legs (peripheral neuropathy). Call your healthcare provider if you have any of these symptoms.

Tell your healthcare provider right away if you have any of the symptoms listed above.

The most common, but less serious side effects of PEGASYS include:

- **flu-like symptoms.** Symptoms may include: fever, chills, muscle aches, joint pain, and headaches. Some of these symptoms may be decreased by injecting your PEGASYS dose in the evening. Talk to your healthcare provider about which over-the-counter medicines you can take to help prevent or decrease some of the symptoms.
- **tiredness and weakness.** Many people become very tired or feel weak while taking PEGASYS.
- **stomach problems.** Nausea and vomiting may happen with PEGASYS.
- **loss of appetite**
- **skin reactions.** Some people may develop redness, swelling, dry or itchy skin at the site of injection. If after several days these symptoms do not disappear, contact your healthcare provider.
- **hair thinning.** Temporary hair loss is not uncommon during treatment with PEGASYS.
- **trouble sleeping**

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 side effects of PEGASYS. 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 PEGASYS?

- Store PEGASYS single use vials, prefilled syringes, and autoinjectors in a refrigerator, at 36°F to 46°F (2°C to 8°C). Do not leave PEGASYS out of the refrigerator for more than 24 hours.
- Do not freeze or shake PEGASYS.
- Protect PEGASYS from light.

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

General information about PEGASYS.

It is not known if treatment 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 PEGASYS for a condition for which it was not prescribed. Do not give PEGASYS 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 PEGASYS. If you would like more information about PEGASYS, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information that is written for health professionals.

What are the ingredients in PEGASYS?

Active ingredient: interferon alfa-2a

Inactive ingredients: acetic acid, benzyl alcohol, polysorbate 80, sodium acetate trihydrate, and sodium chloride.

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

MG Revised: 9/2014

PEGASYS is a trademark of Hoffmann-La Roche Inc.

Manufactured by:

Hoffmann-La Roche, Inc.

c/o Genentech, Inc.

A Member of the Roche Group

1 DNA Way

South San Francisco, CA 94080-4990

Distributed by:

Genentech USA, Inc.

A Member of the Roche Group

1 DNA Way

South San Francisco, CA 94080-4990

© 2014 Genentech, Inc. All rights reserved.