

Patients should be informed that it is not known if therapy with PEGASYS alone or in combination with COPEGUS will prevent transmission of HCV or HBV infection to others or prevent cirrhosis, liver failure or liver cancer that might result from HCV or HBV infection. Patients who develop dizziness, confusion, somnolence, and fatigue should be cautioned to avoid driving or operating machinery.

Patients should be advised to avoid drinking alcohol to reduce the chance of further injury to the liver.

Patients should not switch to another brand of interferon without consulting their healthcare provider.

### Dosing Instructions

Patients should be advised to take their prescribed dose of PEGASYS on the same day and approximately same time each week. Patients should also be advised that if they miss a dose, but remember within 2 days, to take their missed dose as soon as they remember and then to take their next dose on the day they normally do. If they remember when more than 2 days have passed, patients should be advised to consult their healthcare provider.

Patients must be instructed on the use of aseptic techniques when administering PEGASYS. Appropriate training for preparation using the vial or syringe must be given by a healthcare provider, including a careful review of the PEGASYS Medication Guide and Medication Guide Appendix: Instructions for Preparing and Giving a Dose with a PEGASYS® Prefilled Syringe and Appendix: Instructions for Use PEGASYS® Solution for Injection Vial.

Patients should be instructed to allow the vial or prefilled syringe to come to room temperature and for condensation on the outside of the syringe to disappear before use. Patients should be advised not to shake the vial or prefilled syringe as foaming may occur.

Patients should be advised to choose a different place on either the thigh or abdomen each time an injection is made.

## **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 COPEGUS, also read the Medication Guide for COPEGUS (ribavirin) Tablets.**

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

- 1. COPEGUS 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/COPEGUS combination therapy. You or your sexual partner should not become pregnant while you take PEGASYS/COPEGUS 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/COPEGUS combination therapy and for the 6 months after treatment.

- Females must have a pregnancy test before starting PEGASYS/COPEGUS combination therapy, every month while being treated, and every month for the 6 months after treatment with PEGASYS/COPEGUS combination therapy.
- **If you or your female sexual partner becomes pregnant** while taking PEGASYS/COPEGUS or within 6 months after you stop taking PEGASYS/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 PEGASYS/COPEGUS 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 cells 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 COPEGUS to treat adults who have chronic (lasting a long time) hepatitis C infection and certain types of liver problems, and who have not taken alpha interferon
- if you have chronic hepatitis C, you should not take PEGASYS by itself unless you are not able to take COPEGUS
- used to treat adults with chronic hepatitis B.

It is not known if PEGASYS is safe and will work in children under 18 years 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 COPEGUS 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 COPEGUS or during the 6 months after your treatment has ended
- have certain blood disorders such as thalassemia major or sickle-cell anemia.
- take didanosine (Videx or Videx EC)

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 breast-feeding 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 breast-feed. 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, Uniphyll, 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, Nalophine hydrochloride)
- azathioprine (Azasan, Imuran)

**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.
- 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.

- Your healthcare provider should show you how to prepare and measure your dose of PEGASYS, and how to inject yourself before you use PEGASYS for the first time.
- PEGASYS comes as a liquid:
  - in a single use vial
  - in a prefilled syringe

Your healthcare provider will decide which one is best for you. **See the Instructions for Use at the end of this Medication Guide for detailed instructions for preparing and injecting a dose of PEGASYS.**

- Do not re-use PEGASYS single use vials, prefilled syringes, 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, alone or in combination with COPEGUS, 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 COPEGUS?**

- If you are pregnant do not start taking or continue taking PEGASYS alone or in combination with COPEGUS. (See **“What is the most important information I should know about PEGASYS?”**). COPEGUS 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 COPEGUS. PEGASYS, alone or in combination with COPEGUS, 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 breast-feed your baby while on PEGASYS, alone or in combination with COPEGUS.
- Drinking alcohol, including beer, wine and liquor. This may make your liver disease worse.
- Taking other medicines. Take only medicines prescribed or approved by your healthcare provider. These include prescription and nonprescription 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

- **Nerve problems.** People who take PEGASYS or other alpha 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 and prefilled syringes in a refrigerator, at 36°F to 46°F (20°C to 80°C).
- Do not freeze or shake PEGASYS.
- Protect PEGASYS from light.

Keep PEGASYS vials, prefilled syringes, and all medicines out of the reach of children.

#### **General information about PEGASYS**

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

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

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

## Medication Guide Appendix: Instructions for Use

### Solution for Injection Prefilled Syringe

Be sure that you read, understand and follow these instructions before injecting PEGASYS. Your healthcare provider should show you how to prepare, measure and inject PEGASYS properly before you use it for the first time. Ask your healthcare provider if you have any questions.

Pegasys prefilled syringes come in a Monthly Convenience Pack that contains 4 prefilled syringes of PEGASYS in a box with 4 needles and 4 alcohol pads. Each needle has a needle-stick protection device.

Before starting, collect all of the supplies that you will need to use for preparing and injecting PEGASYS. You will need the following supplies:

- 1 single-use disposable prefilled syringe of PEGASYS
- 1 needle with needle-stick protection device
- 1 alcohol pad

You will also need a puncture-proof disposable container to throw away used prefilled syringes and needles.

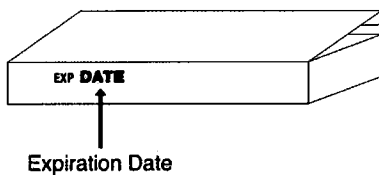
#### Important:

- Never re-use disposable prefilled syringes and needles.
- Throw away the prefilled syringe of PEGASYS after you use it 1 time
- Do not shake PEGASYS. If shaken, PEGASYS may not work properly.

#### How should I prepare a dose of PEGASYS?

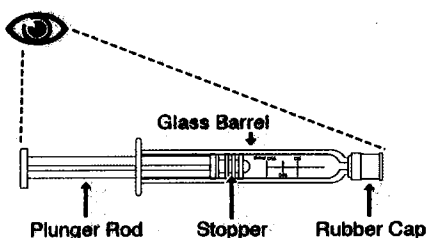
1. Find a well lit, clean flat working surface such as a table.
2. Take a carton containing PEGASYS out of the refrigerator. Check the date on the carton the PEGASYS comes in. Make sure the expiration date has not passed. Do not use if the expiration date has passed (see Figure 1).

**Figure 1:**



3. Remove the prefilled syringe of PEGASYS from the carton. Look at the prefilled syringe of PEGASYS. The solution should be clear and colorless to light yellow, without particles (see Figure 2), if there is foam in the solution, put it back in the refrigerator for use at a later time and use another syringe.

**Figure 2:**

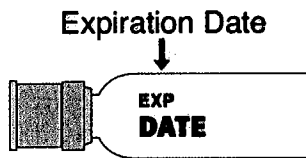




Do not use the prefilled syringe of PEGASYS if:

- the medicine remains cloudy after a few minutes at room temperature
- has particles
- the medicine is not colorless to light yellow
- the expiration date has passed

**Figure 3:**

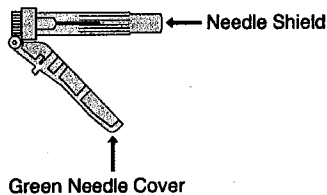


4. Wash your hands well with soap and warm water. Keep your work area, your hands, and injection site clean to decrease the risk of infection.
5. Lay the syringe on a flat clean surface and wait a few minutes until it reaches room temperature. If you notice condensation water on the outside of the syringe, wait another few minutes until it disappears.

**How do I attach the needle to the PEGASYS prefilled syringe?**

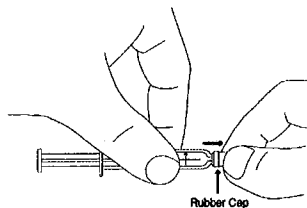
6. Remove the needle from its package. Do not remove the needle shield yet. Keep the needle covered until just before you give the injection (see Figure 4).

**Figure 4:**



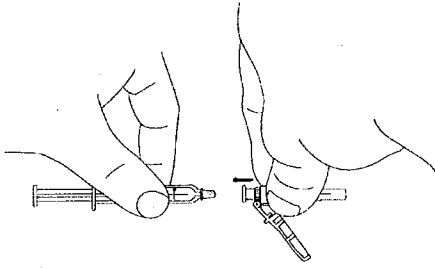
7. Remove and throw away the rubber cap from the tip of the syringe barrel (see Figure 5).

**Figure 5:**



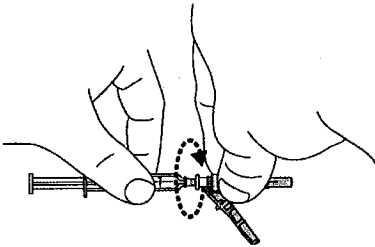
8. With one hand, hold the syringe by the barrel. With your other hand, hold the needle close to the hub where the green needle cover connects to the syringe (see Figure 6).

**Figure 6:**



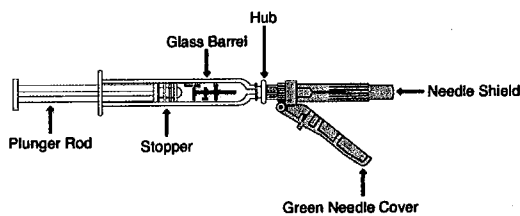
9. Push the needle onto the syringe and tighten by using an easy twisting motion in the direction of the arrow (see Figure 7).

**Figure 7:**



Here is a picture of what the syringe will look like after you finish attaching the needle (see Figure 8).

**Figure 8:**

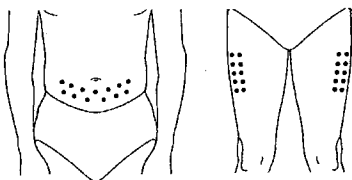


10. Lay the syringe and needle down on your clean work surface. Be sure that the plastic needle shield covers the needle. Never let the needle touch any surface.

**How should I choose a site for injection?**

11. You can inject PEGASYS under the skin on your stomach or thigh (see Figure 9). Avoid your navel and waistline. You should use a different place each time you give yourself an injection.

**Figure 9:**

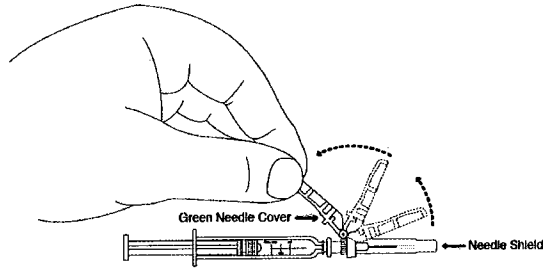


12. Clean the area using the alcohol pad. Let the skin air dry.

## How do I prepare the PEGASYS prefilled syringe for injection?

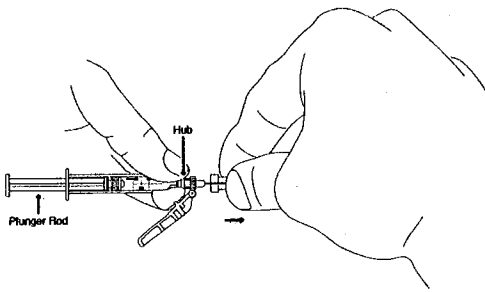
13. Pull the green needle cover back from the needle toward the syringe barrel. The green needle cover will stay in the position you set. Do not remove it. This is the needle-stick protection device (see Figure 10).

**Figure 10:**



14. Hold the syringe and needle tightly at the hub. Gently rock the plastic needle shield back and forth to prepare for removal. Remove the plastic needle shield by pulling it straight off (see Figure 11).

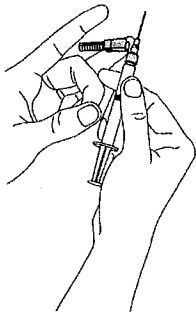
**Figure 11:**



15. Remove air bubbles from the syringe.

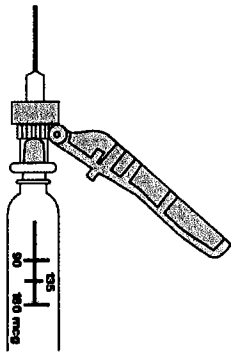
- Hold the syringe with the needle pointing up to the ceiling.
- Using your thumb and finger, gently tap the syringe to bring air bubbles to the top (see Figure 12).
- Press the plunger in slightly to push air bubbles out of the syringe.

**Figure 12:**

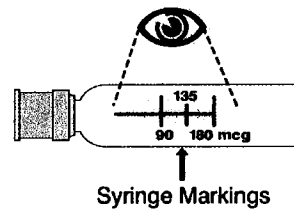


16. Depending on the dose of PEGASYS that your healthcare provider prescribes, you may have to get rid of (discard) some of the medicine from the prefilled syringe before you inject the medicine. The syringe has markings for 180 mcg, 135 mcg, and 90 mcg. Your healthcare provider will tell you which mark to use (see Figure 13 and Figure 14).

**Figure 13:**



**Figure 14:**

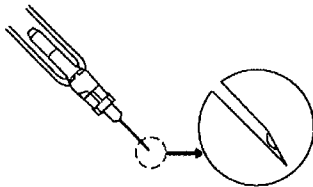


Do not decrease or increase your dose of PEGASYS unless your healthcare provider tells you to.

### **How Do I Give the Injection of PEGASYS**

17. Position the point of the needle (the bevel) so it is facing up (see Figure 15).

**Figure 15:**



18. Pinch a fold of skin on your stomach or thigh firmly with your thumb and forefinger (see Figure 16).

**Figure 16:**



19. Hold the syringe like a pencil at a 45° to 90° angle to your skin. With a quick “dart-like” motion, push the needle into the skin as far as it will go (see Figure 17).

**Figure 17:**



20. After the needle is inserted, remove the hand used to pinch the skin and use it to hold the syringe barrel.

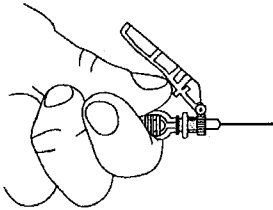
- Pull the plunger of the syringe back slightly.
- **If blood comes into the syringe**, the needle has entered a blood vessel.
  - Do not inject PEGASYS. Withdraw the needle and throw away the syringe and needle in the puncture-proof container. See “How should I dispose of used syringes and needles?”
  - Then, repeat steps 1 through 16 with a new prefilled syringe and prepare a new injection site.

- **If no blood is present in the syringe**, inject the medicine by gently pressing the plunger all the way down the syringe barrel, until the syringe is empty.

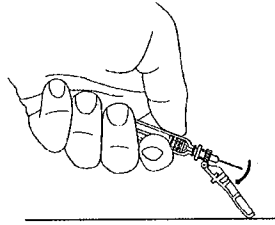
21. When the syringe is empty, pull the needle out of the skin. Wipe the area with an alcohol pad.

22. To prevent needle-stick injuries, before you dispose of the syringe and needle, push the green needle cover toward the needle (see Figure 18). Then place the free end of the green cap on a flat surface and push gently down on it until it clicks and covers over the needle (see Figure 19).

**Figure 18:**



**Figure 19:**



23. Throw away the used syringe and needle. See “How should I dispose of used syringes and needles?”

#### **How should I dispose of used syringes and needles?**

- Do not re-use needles and syringes
- Throw away used syringes and needles in a puncture-proof container, sharps container
- Check with your healthcare provider for instructions about the right way to throw away used needles and syringes. There may be local or state laws about how to throw away used needles and syringes.
- Do not throw away used needles and syringes or the puncture-proof container in household trash and do not recycle them.
- Dispose of the full container as instructed by your health care provider or pharmacist.

Always keep the puncture-proof container out of the reach of children.

#### **How should I store PEGASYS?**

- Store PEGASYS prefilled syringes in a refrigerator, at 36°F to 46°F (20°C to 8°C).
- Do not freeze or shake PEGASYS.
- Protect PEGASYS from light.

MG Appendix: Prefilled Syringe revision date: February 2011

## Medication Guide Appendix: Instructions for Use

### Solution for Injection Vial

Be sure that you read, understand and follow these instructions before injecting PEGASYS. Your healthcare provider should show you how to prepare, measure, and inject PEGASYS properly before you use it for the first time. Ask your healthcare provider if you have any questions.

Before starting, collect all of the supplies that you will need to use for preparing and injecting PEGASYS. You will need the following supplies:

- 1 vial of PEGASYS
- 1 single-use disposable syringe and needle
- several alcohol pads

You will also need a puncture-proof container to throw away used syringes, needles, and vials.

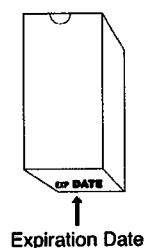
#### Important:

- Never re-use disposable syringes and needles.
- Throw away the vial of PEGASYS after you use it 1 time even if there is medicine left in the vial.
- Make sure you have the right syringe and needle to use with PEGASYS. Your healthcare provider should tell you what syringes and needles you should use and where to buy them.
- Do not shake PEGASYS. If shaken, PEGASYS may not work properly.

#### How should I prepare a dose of PEGASYS?

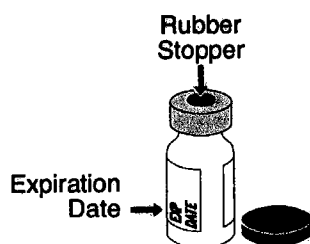
1. Find a well lit, clean flat working surface such as a table.
2. Take a carton containing PEGASYS out of the refrigerator. Check the date on the carton the PEGASYS comes in. Make sure the expiration date has not passed. Do not use if the expiration date has passed (see Figure 1).

**Figure 1:**



3. Wash your hands well with soap and warm water. Keep your work area, your hands, and injection site clean to decrease the risk of infection.
4. Remove the vial of PEGASYS from the carton. Look at the vial of PEGASYS. The solution should be clear and colorless, without particles (see Figure 2).

**Figure 2:**



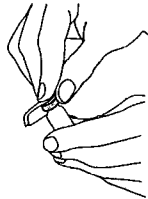
Do not use the vial of PEGASYS if

- the medicine is cloudy
  - has particles
  - the medicine is not colorless to light yellow.
  - the expiration date has passed
5. Warm the refrigerated medicine by gently rolling it in the palms of your hands for about one minute. Do not shake PEGASYS.
  6. Remove (flip off) the plastic cap from the top of the PEGASYS vial (see Figure 3). Clean the rubber stopper on the top of the vial with an alcohol pad (see Figure 4).

**Figure 3:**



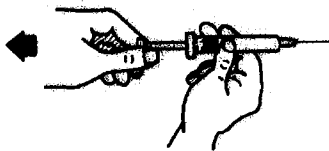
**Figure 4:**



If you are not sure how much medicine to use or which mark on the syringe to use, stop and call your healthcare provider right away.

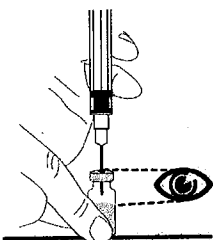
7. Open the package for the syringe you are using and if it does not have a needle attached, then attach a new needle to the syringe.
8. Remove the protective cap from the needle on the syringe. Never let the needle touch any surface. Fill the syringe with air by pulling back on the plunger to the mark on the syringe barrel that matches the dose prescribed by your healthcare provider (see Figure 5).

**Figure 5:**



9. Hold the vial of PEGASYS on your flat working surface. Do not touch the cleaned rubber stopper.
10. Push the needle straight down through the middle of the rubber stopper on the vial. Slowly inject all the air from the syringe into the air space above the solution. Do not inject air into the fluid (see Figure 6).

**Figure 6:**



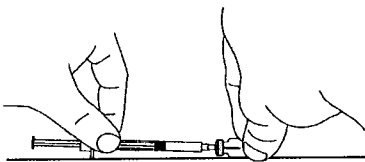
11. Keep the needle in the vial. Turn the vial upside down.
  - Make sure the tip of the needle is in the PEGASYS solution.
  - Slowly pull the plunger back to fill the syringe with PEGASYS solution to the dose (mL or cc markings on the syringe) that matches the dose prescribed by your healthcare provider (see Figure 7).

**Figure 7:**



12. Do not remove the needle from the vial. Lay the vial and syringe on its side on your flat work surface until you are ready to inject the PEGASYS solution (see Figure 8).

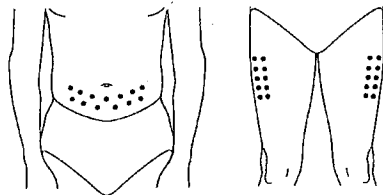
**Figure 8:**



### **How should I choose a site for injection?**

13. You can inject PEGASYS under the skin on your stomach or thigh (see Figure 9). Avoid your navel and waistline. You should use a different place each time you give yourself an injection.

**Figure 9:**



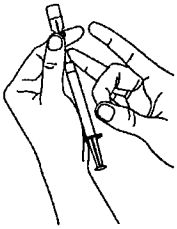
14. Clean the area using an alcohol pad. Let the skin air dry.

### **How should I give an injection?**

15. Pick up the vial and syringe from your flat work surface. Remove the syringe and needle from the vial.
  - Hold the syringe in the hand that you will use to inject PEGASYS.
  - Do not touch the needle or allow it to touch the work surface.
16. Remove air bubbles from the syringe.
  - Hold the syringe with the needle pointing up to the ceiling.
  - Using your thumb and finger, tap the syringe to bring air bubbles to the top (see Figure 10).
  - Press the plunger in slightly to push air bubbles out of the syringe.

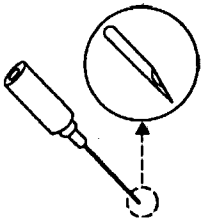
**Figure 10:**





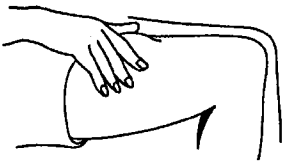
17. Position the point of the needle (the bevel) so it is facing up (see Figure 11).

**Figure 11:**



18. Pinch a fold of skin on your stomach or thigh firmly between your thumb and forefinger (see Figure 12).

**Figure 12:**



19. Hold the syringe like a pencil at a 45° to 90° angle to your skin. With a quick “dart-like” motion, push the needle into the skin as far as it will go (see Figure 13).

**Figure 13:**



20. After the needle is inserted, remove the hand used to pinch the skin and use it to hold the syringe barrel.

- Pull the plunger of the syringe back slightly.
- **If blood comes into the syringe**, the needle has entered a blood vessel.
  - Do not inject PEGASYS. Withdraw the needle and throw away the syringe, needle, and vial in the puncture-proof container. See “How should I dispose of used syringes, needles, and vials?”
  - Then, repeat steps 1 through 19 with a new vial of PEGASYS and inject the medicine at a new injection site.
- **If no blood is present in the syringe**, inject the medicine by gently pressing the plunger all the way down the syringe barrel, until the syringe is empty.

21. When the syringe is empty, pull the needle out of the skin. Wipe the area with an alcohol pad.

22. Throw away the used syringe, needle, and vial. See “How should I dispose of used syringes, needles, and vials?”

**How should I dispose of used syringes, needles, and vials?**

- Do not re-use needles, syringes, or vials.
- Throw away used syringes, needles, and vials in a puncture-proof container, sharps container.
- Check with your healthcare provider for instructions about the right way to throw away used needles and syringes. There may be local or state laws about how to throw away used needles and syringes.
- Do not throw away used needles, syringes, vials, or the puncture-proof container in household trash and do not recycle them.
- Dispose of the full container as instructed by your healthcare provider or pharmacist.
- Always keep the puncture-proof container out of the reach of children.

**How should I store PEGASYS?**

- Store PEGASYS single use vials in a refrigerator, at 36°F to 46 °F (2°C to 8°C).
- Do not freeze or shake PEGASYS.
- Protect PEGASYS from light.

MG Appendix: Vial revision date: February 2011

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**Hoffmann-La Roche Inc.**

340 Kingsland Street

Nutley, NJ 07110-1199

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1 DNA Way  
South San Francisco, CA 94080-4990

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