

PRODUCT MONOGRAPH

PrPEGASYS®

peginterferon alfa-2a injection

Pre-filled syringes: 180 mcg/0.5 mL

Single-use Vials: 180 mcg/1 mL

Biological Response Modifier

Professed Standard

Hoffmann-La Roche Limited
2455 Meadowpine Boulevard
Mississauga, Ontario, Canada
L5N 6L7

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www.rochecanada.com

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PART III: CONSUMER INFORMATION**PrPEGASYS®
(Peginterferon alfa-2a)**

This leaflet is part III of a three-part “Product Monograph” published when PEGASYS was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PEGASYS. Contact your doctor or pharmacist if you have any questions about the drug.

You have been prescribed PEGASYS (pronounced PEG-ah-sis) by your doctor to treat your Hepatitis C or Hepatitis B liver infection. Reading this information can help you learn about PEGASYS and how to make this medicine work best for you.

Before starting on this medication, please read this leaflet carefully and make sure that you have all supplies needed on hand. Please discuss the supplies you need with your doctor.

ABOUT THIS MEDICATION**What the medication is used for:**

PEGASYS (peginterferon alfa-2a) is used for the treatment of chronic hepatitis C in:

- Adult patients without cirrhosis
- Adult patients with compensated cirrhosis,

including HCV/HIV co-infection patients with stable HIV disease with or without antiretroviral therapy.

PEGASYS is indicated for the treatment of both HBeAg-positive and HBeAg-negative chronic hepatitis B in:

- Patients with compensated liver disease, liver inflammation and evidence of viral replication (both cirrhotic and non-cirrhotic disease).

What it does:

PEGASYS is a prescription medication belonging to the family of drugs called interferons. “Interferon” refers to a kind of protein normally made in a person’s body. Interferons are a normal part of your body’s defense system for fighting disease. Scientists can also make interferons outside of the body for use as medicines. Another name for PEGASYS is peginterferon alfa-2a. PEGASYS is a modified interferon that is different from the interferon made in a person’s body. This modification helps the interferon (PEGASYS) stay in your body for a prolonged time and allows PEGASYS to be injected only once a week.

No one knows exactly how interferons work. However, treatment with PEGASYS increases your body’s natural defense system for fighting disease.

What is Hepatitis C?

Hepatitis C is a liver disease caused by the hepatitis C virus. Hepatitis C is spread by contact with blood of a person carrying the hepatitis C virus.

Hepatitis C is more serious for some people than others. Most people who get hepatitis C carry the virus in their blood for the rest of their lives. Most of these people will have some liver damage, but many do not feel sick from the disease. In some people, the liver becomes badly damaged and scarred. This is called cirrhosis. Cirrhosis can cause the liver to stop working properly.

With PEGASYS therapy, the hepatitis C virus can be decreased to a level so low that it cannot be measured by blood tests. The virus is decreased and cannot be measured in 3 to 4 out of every 10 people who take PEGASYS therapy for approximately one year.

Your healthcare provider will monitor the effects of your medicine on your body through blood tests. While you are using PEGASYS, it is very important to get the blood tests your doctor orders. This will help your doctor see how well the medicine is working for you.

If you have any questions about your health conditions or PEGASYS, talk to your healthcare provider.

What is Hepatitis B?

Hepatitis B is a liver disease caused by the hepatitis B virus. Hepatitis B is spread by contact with blood and/or bodily fluids of a person carrying the hepatitis B virus.

Hepatitis B is more serious for some people than others. Most people who become infected never feel sick and recover completely; however, some people who get hepatitis B carry the virus in their blood for the rest of their lives even if they are symptom free. Some adults develop a chronic disease, which can lead to the liver being badly damaged and scarred (a condition called cirrhosis) and cancer of the liver later in life.

With PEGASYS treatment, you will have regular blood tests to help your healthcare provider check how the treatment is working and to check for side effects.

If you have questions about your health condition or PEGASYS, talk to your healthcare provider.

When it should not be used:

- you ever had an allergic reaction to other alpha interferons, or any of the ingredients in PEGASYS.
- you have autoimmune hepatitis (hepatitis caused by your immune system attacking your liver).
- you have unstable or advanced liver disease.
- you are coinfecting with HIV and you have unstable or advanced liver disease, as determined by your doctor.
- neonates and infants because the PEGASYS component contains benzyl alcohol. There have been rare reports of death in neonates and infants associated with excessive exposure to benzyl alcohol. The amount of benzyl alcohol at which toxicity or adverse effects may occur in neonates or infants is not known.

What the medicinal ingredient is:

Peginterferon alfa-2a

What the nonmedicinal ingredients are:

Acetic acid, benzyl alcohol, polysorbate 80, sodium acetate trihydrate, sodium chloride and water for injection.

What dosage forms it comes in:

Pre filled Syringes: Each syringe contains 180 mcg of PEGASYS in a 0.5 mL volume.

Vials: Each vial contains 180 mcg of PEGASYS in a 1 mL volume.

WARNINGS AND PRECAUTIONS

BEFORE you use PEGASYS talk to your doctor or pharmacist if:

- **you are pregnant or breast-feeding or are planning to become pregnant.**
- you have a history of or current mental illness (such as depression or anxiety).
- you have a history of drug or alcohol addiction or abuse.
- you have high blood pressure or a history of heart disease or previous heart attack or high blood fat (such as elevated triglyceride or cholesterol levels).
- you have a history of cancer.
- you have kidney problems.
- you have blood disorders, including anemia (low red blood cell count), thalassemia (Mediterranean anemia) and sickle-cell anemia
- you are taking any other medicines, including those not prescribed by your doctor. Your doctor should know if you are taking medicines called methadone or theophylline.
- you are taking the Chinese herbal medicine sho-saiko-to, also known as Xiao-Chai-Hu.

- you have had an organ transplant and are taking medicine that keeps your body from rejecting your transplant (suppresses your immune system).
- you have diabetes (high blood sugar).
- you have problems with your thyroid gland.
- you have liver problems (other than hepatitis C or hepatitis B)

This information will help your doctor and you decide whether you should use PEGASYS and what extra care may need to be taken while you are on these medicine. If you have any doubts about your health condition or about taking PEGASYS, talk to your doctor.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PEGASYS include: methadone, sho-saiko-to/Xiao-Chai-Hu and theophylline.

Tell your doctor or pharmacist if you are taking Sebivo (telbivudine) for chronic hepatitis B because taking this medicine together with PEGASYS may increase your risk of developing peripheral neuropathy (numbness, weakness, tingling, and/or burning sensations, or pain in the arms and/or legs). The combined use of these medications is not recommended.

PROPER USE OF THIS MEDICATION

Usual dose:

How should you take PEGASYS?

Your doctor has prescribed PEGASYS after carefully studying your case. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours. Do not give your PEGASYS to anyone else.

PEGASYS is given as an injection just under the skin, on the stomach or thighs. You may hear people call this type of injection a “subcutaneous” or “Sub Q” injection. This means that the injection goes into the layer of fat just under the skin. If you have any questions about how to take PEGASYS or have trouble giving yourself the injections, call your doctor immediately.

Your healthcare provider will tell you how much medicine to take and how often to take it. PEGASYS is a ready-to-use solution usually given as a single injection once per week. Make sure that you drink plenty of fluids while you are being treated with PEGASYS.

PEGASYS is supplied in two different ways: pre-filled syringes and vials. It is important that you follow the **specific** instructions for using the kind of PEGASYS that your doctor has prescribed. **Whether you give yourself the injection, or another person gives the injection to you, it is important to follow the instructions (see Appendix 1 - How to use) in this information sheet.**

How long will you have to take PEGASYS?

Your doctor will tell you how long you need to use PEGASYS. Over time, your doctor may change your dose of PEGASYS. For information on how to change your dose of PEGASYS, see the section called “**How do you use PEGASYS?**” Only change your dose of PEGASYS if your doctor tells you to change it.

After 3 months of therapy, your doctor may ask you to have a blood test to determine how you are responding to your treatment.

What should you do if your doctor changes your dose of PEGASYS?

If your doctor changes your dose of PEGASYS, you will need to pull a different amount of medicine into the syringe from the vial. Your doctor will tell you which mark on the syringe to use. Do not change your dose of PEGASYS unless your doctor tells you to.

If you ever switch between using pre-filled syringes and vials, talk to your healthcare provider about how much PEGASYS to use. Equal volumes of liquid from the pre-filled syringes and the vials DO NOT contain the same amount of PEGASYS. If you switch between pre-filled syringes and vials, you will have to adjust the volume of liquid that you use to give your injection. If you do not adjust this, you could accidentally take too much or too little of your medicine.

Are all interferons the same?

Once you start treatment with PEGASYS, do not switch to another brand of interferon and/or ribavirin without talking to your doctor. Other brands may not have the same effect on the treatment of your disease. Switching brands will also require a change in your dose.

Overdose:

If you take more than the prescribed amount of PEGASYS, call your doctor right away. Your doctor may want to examine you and take blood for testing.

Missed Dose:

If you miss a dose of PEGASYS and remember **within 2 days** of the scheduled dose, give yourself an injection of PEGASYS as soon as you remember. Take your next PEGASYS dose on the day you would usually take it. If **more than 2 days have passed**, ask your doctor what you should do.

To get the most benefit from this medicine, it is important to take PEGASYS exactly as your doctor and healthcare providers tell you.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unwanted effects are possible with all medicines. PEGASYS can cause some serious side effects. Before starting PEGASYS, you should talk with your doctor

about the possible benefits and possible side effects of treatment. Talk to your doctor or pharmacist if you are worried about side effects or find them very bothersome. There may be a way to relieve your symptoms. While taking PEGASYS, you will need to see your doctor regularly for medical examinations and blood tests to make sure your treatment is working and to check for side effects.

The most common side effects of interferon therapy, including PEGASYS are:

- Flu-like symptoms such as unusual tiredness, fever, chills, muscle aches, joint pain, and headaches. Most people have mild to moderate flu-like symptoms, but these usually decrease after the first few weeks of treatment. Taking acetaminophen (e.g. Tylenol®) or ibuprofen (e.g. Advil®) before you take PEGASYS can help with these symptoms. Ask your pharmacist or doctor for a recommendation as to which pain reliever to take. You can also try taking PEGASYS at night. You may be able to sleep through the symptoms.

Other common side effects can occur with PEGASYS, but are usually mild. These may include:

- Upset stomach, nausea, vomiting, loss of appetite, diarrhea, back pain, trouble sleeping, poor concentration, dizziness, decreased sexual desire, numbness or tingling, rash, dry itchy skin, hair thinning, redness and swelling at the injection site, problems with blood sugar, feeling tired and cough.

The serious possible side effects of interferon therapy, including PEGASYS are:

- Mood or behavioral problems including irritability (getting easily upset), depression (feeling low, feeling bad about yourself or feeling hopeless), and anxiety. Some patients may have aggressive behaviour or develop thoughts about ending their lives (suicidal thoughts) and may attempt to do so. A few patients have ended their lives.
- A drop in the number of white blood cells causing a risk for infection, and drop in platelets resulting in bleeding if the numbers drop too low.
- Serious infections (bacterial, viral or fungal).
- Lung problems (such as difficulty breathing or pneumonia) and eye problems that may cause blurred vision, a visual field deficit, or loss of vision.
- Autoimmune problems (where the body’s own immune system begins to attack itself) including psoriasis or thyroid problems.
- Chest pain and very rarely heart attack.
- If you have chronic hepatitis B: A rise in a blood test that measures your liver function.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Call your doctor or pharmacist	
	Only if severe	In all cases		
Less Common	Depressed or think of suicide		<input checked="" type="checkbox"/>	
	Experience hallucinations, aggressiveness or confusion, or have trouble sleeping or concentrating		<input checked="" type="checkbox"/>	
	Severe chest pain or irregular heart beat		<input checked="" type="checkbox"/>	
	Trouble breathing or persistent cough		<input checked="" type="checkbox"/>	
	A problem with your eyesight, a change in your vision (such as blurred vision, a visual field deficit or loss of vision), or hearing problem		<input checked="" type="checkbox"/>	
	Unusual bleeding or bruising including severe nosebleeds		<input checked="" type="checkbox"/>	
	Psoriasis (skin disease) and it gets worse while taking medicine		<input checked="" type="checkbox"/>	
	Serious skin rash, hives, swelling or itching		<input checked="" type="checkbox"/>	
	High fever or chills, or have pain when urinating		<input checked="" type="checkbox"/>	
	Severe stomach pain or lower back pain		<input checked="" type="checkbox"/>	
	Bloody diarrhea		<input checked="" type="checkbox"/>	
	Woman and become pregnant		<input checked="" type="checkbox"/>	

If you are concerned about these or any other unexpected effects while on PEGASYS, talk to your doctor or pharmacist.

HOW TO STORE IT

PEGASYS must be stored in the refrigerator at a temperature of 2°C to 8°C. Do not freeze PEGASYS. Keeping PEGASYS at temperatures outside the recommended range can destroy the medicine.

Do not shake PEGASYS. Shaking can destroy PEGASYS so that it will not work.

Protect PEGASYS from light during storage.

Do not use after expiry date stated on the label.

Keep this and all other medicines out of the reach of children.

Appendix 1 How to Use

What is the safe way to handle and dispose of PEGASYS?

If you use PEGASYS at home, you must throw away syringes and needles in a box that will not let the needles stick through it. This will help protect you and other people from accidental needle sticks. Being stuck by a needle not only hurts, but also can pass diseases on to other people.

You can get these special boxes, often called “puncture-resistant containers,” from your doctor or pharmacist. When the box is full, follow your healthcare provider’s instructions for throwing it away.

For safety reasons, always throw away syringes and needles promptly and never reuse them.

How do you use PEGASYS?

Please ask your doctor what supplies you need for properly administering this drug.

Pre filled Syringes:

The following instructions will help you learn how to use PEGASYS pre-filled syringes to inject yourself. It is important to follow these directions carefully. Talk to your healthcare provider if you have any concerns about how to use PEGASYS.

If you are giving this injection to someone else, a healthcare provider must teach you how to avoid needle sticks. Being stuck by a needle can pass diseases on to you.

Getting ready

Wash your hands carefully before handling any of the items.

Collect the necessary items before beginning:

Included in the pack:

- a pre-filled syringe of PEGASYS
- an injection needle*

Not included in the pack:

- alcohol swabs
- small bandage or sterile gauze
- a puncture-resistant container for cleaning up when you are finished

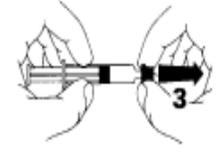
You may need to purchase these.

Preparing the syringe and needle for injection

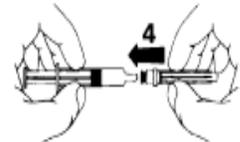
- Remove the protective cap that covers the back of the needle (1-2)



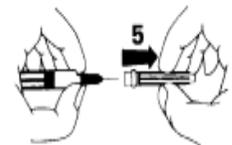
- Remove the rubber cap from the syringe (3). Do not touch the tip of the syringe.



- Place the needle firmly on the tip of the syringe (4).



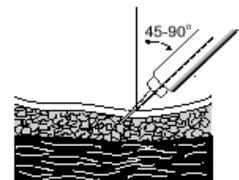
- Remove the needle guard from the syringe needle (5).



- To remove air bubbles from the syringe, hold the syringe with the needle pointing up. Tap the syringe gently to bring the bubbles to the top. Push the plunger up slowly to the correct dose. Replace the needle guard and place the syringe in a horizontal position until ready for use.
- Allow the solution to reach room temperature before injection or warm the syringe between your palms.
- Visually inspect the solution prior to administration. Do not use if it is discoloured (any colour besides colourless to light yellow) or if particles are present and report the lot number to your healthcare provider.
- You are now ready to inject the dose.

Injecting the solution

- Select the injection site in the abdomen or thigh (except your navel or waistline). Change your injection site each time.
- Clean and disinfect the skin where the injection is to be made with an alcohol swab.
- Wait for the area to dry.
- Remove the needle guard.
- With one hand, pinch a fold of loose skin. With your other hand hold the syringe as you would a pencil.
- Insert the needle all the way into the pinched skin at an angle of 45° to 90° (6).



- Inject the solution by gently pushing the plunger all the way down.

- Pull the needle straight out of the skin.

Disposal of the injection materials

- Clean up after your injection
- Place the syringe and needle in a puncture-resistant container immediately after use.
- Throw away full containers according to directions provided by your healthcare provider.

Vials:

The following instructions will help you learn how to use PEGASYS vials to inject yourself. Please read all of these directions before trying to take your medicine. It is important to follow these directions carefully. Talk to your healthcare provider if you have any concerns about how to use PEGASYS.

If you are giving this injection to someone else, a healthcare provider must teach you how to avoid needle sticks. Being stuck by a needle can pass diseases on to you.

Getting ready

Wash your hands carefully before handling any of the items. Collect the necessary items before beginning.

Included in the pack:

- a vial of PEGASYS solution for injection.

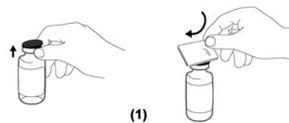
Not included in the pack:

- alcohol swabs
- 1 mL syringe and needle (recommended: 27 gauge x ½ inch) for subcutaneous administration
- small bandage or sterile gauze
- a puncture-resistant container for cleaning up when you are finished.

You may need to purchase these.

Measuring the dose of PEGASYS

- Remove the protective cap from the PEGASYS vial (1).
- Clean the rubber top of the vial with an alcohol swab.

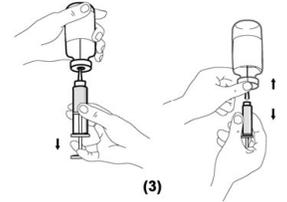


- Remove the needle and syringe from their packaging.
- Pull the syringe plunger back to the mark on the syringe barrel as instructed; this will pull air into the syringe barrel.
- Remove the needle guard without touching the needle and insert through the center of the stopper on the PEGASYS vial.

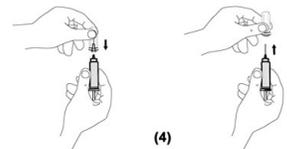
- Slowly inject all the air from the syringe into the air space above the solution. Do not inject air into the fluid (2).



- Hold the vial and syringe in one hand and turn the vial and the syringe upside down (3).
- With the syringe pointing up, make certain that the tip of the needle is in the PEGASYS solution. Your other hand will be free to move the plunger of the syringe.



- Slowly pull back on the plunger until the medicine is in the syringe up to the mark specified by your doctor.
- When you have pulled up the medicine to the right mark, pull the syringe needle out of the vial (4).

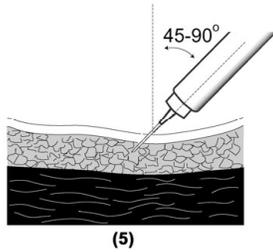


- Check for air bubbles in the syringe. If you see any bubbles, pull the plunger slightly back. To remove air bubbles from the syringe, hold the syringe with the needle pointing up. Tap the syringe gently to bring the bubbles to the top. Push the plunger up slowly to the correct dose. Replace the needle guard and place the syringe in a horizontal position until ready for use.
- Allow the solution to reach room temperature before injection or warm the syringe between your palms.
- Visually inspect the solution prior to administration. Do not use if it is discoloured (any colour besides colourless to light yellow) or if particles are present and report the lot number to your healthcare provider.
- You are now ready to inject the dose.

Injecting the solution

- Select the injection site in the abdomen or thigh (except your navel or waistline). Change your injection site each time.
- Clean and disinfect the skin where the injection is to be made with an alcohol swab.
- Wait for the area to dry.
- Remove the needle guard.
- With one hand, pinch a fold of loose skin. With your other hand hold the syringe as you would a pencil.

- Insert the needle all the way into the pinched skin at an angle of 45° to 90° (5).



- Inject the solution by gently pushing the plunger all the way down.
- Pull the needle straight out of the skin.

Disposal of the injection materials

- Clean up after your injection.
- Place the syringe and needle in a puncture-resistant container immediately after use.
- Throw away full containers according to directions provided by your healthcare provider.

This leaflet does not provide you with all known information about PEGASYS. If you have any questions or concerns about your treatment, please speak with your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone; 866-234-2345
 By toll-free fax: 866-678-6789
 Online: www.healthcanada.gc.ca/medeffect
 By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
 Canada Vigilance National Office
 Marketed Health Products Safety and Effectiveness Information Bureau
 Marketed Health Products Directorate
 Health Products and Food Branch
 Health Canada
 Tunney's Pasture, AL 0701C
 Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

PEGASYS. If you have any further questions or concerns about your treatment with PEGASYS, please contact your doctor or pharmacist.

This document plus the full product monograph, prepared for health professionals can be found at:
www.rochecanada.com

This leaflet was prepared by Hoffmann-La Roche Limited

*Injection needle manufactured by Terumo Europe N. V., Interleuvenlaan 40 Leuven, ZZ, Belgium 3001

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MORE INFORMATION

This brochure does not contain all known information about