

# PRODUCT MONOGRAPH

**Pr**PEGASYS®

peginterferon alfa-2a injection

Pre-filled syringes: 180 mcg/0.5 mL

Single-use Vials: 180 mcg/1 mL

ProClick® Autoinjector: 180 mcg/0.5 mL

Biological Response Modifier

Professed Standard

Hoffmann-La Roche Limited  
7070 Mississauga Road  
Mississauga, Ontario, Canada  
L5N 5M8

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[www.rochecanada.com](http://www.rochecanada.com)

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**PART III: CONSUMER INFORMATION**

**P**PEGASYS®  
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).

PEGASYS is not authorized for use in children and adolescents under the age of 18 years (see SIDE EFFECTS AND WHAT TO DO ABOUT THEM).

**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 have an autoimmune disease (where the body's immune system attacks the body's own cells) such as psoriasis (a skin disease) or sarcoidosis.
- 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.
- you have a history of or current mental illness (such as depression or anxiety). PEGASYS therapy may make them worse. Tell your doctor if you are being treated or had treatment in the past for any mental problems, including depression, thoughts of ending your life (suicidal thoughts) or a feeling of loss of contact with reality, such as hearing voices or seeing things that are not there (psychosis). Tell your doctor if you take any medicines for these problems.
- you have problems with your thyroid gland.
- you are breast feeding.

### **What the medicinal ingredient is:**

peginterferon alfa-2a

### **What the non-medicinal 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.

*ProClick<sup>®</sup> Autoinjector:* Each autoinjector contains 180 mcg of PEGASYS in a 0.5 mL volume.

## **WARNINGS AND PRECAUTIONS**

### **Serious Warnings and Precautions**

**Interferons, including PEGASYS cause or aggravate fatal or life-threatening neuropsychiatric (mental illness), autoimmune (where the body's immune system attacks the body's own cells), ischemic (conditions in which blood flow, and thus oxygen, is restricted to a part of the body) and infectious disorders. If you have persistently severe or worsening signs or symptoms of these conditions you should contact your doctor. Your doctor will assess you and may discontinue you from therapy. In many cases, but not all cases, these disorders resolve after stopping**

## **interferon therapy.**

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)
- you have lung (respiratory) problems, such as pneumonia, shortness of the breath, and Chronic Obstructive Pulmonary Disease (COPD).

*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<sup>®</sup> (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 three different ways: pre-filled syringes, autoinjectors, 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, autoinjectors, and vials, talk to your healthcare provider about how much PEGASYS to use. Equal volumes of liquid from the pre-filled syringes, autoinjectors, 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.

The autoinjector is designed to deliver the full content. If your required dose is not available in an autoinjector, pre-filled syringes or vials should be used.

#### **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.**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

#### **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<sup>®</sup>) or ibuprofen (e.g. Advil<sup>®</sup>) 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 (sometimes directed towards others) or develop thoughts about ending their lives (suicidal thoughts) and may attempt to do so. A few patients have ended their lives.
- Blood related disorders such as pancytopenia (marked decreases in red and white blood cells and platelets) and different forms of anemia
- 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, pneumonia, or high blood pressure of the lungs (pulmonary hypertension).
- 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.
- Stroke: some patients may have weakness, loss of coordination and numbness
- Nerve problems: some patients may have numbness, tingling or burning sensation in the arms or legs
- Effect on growth in children: In a clinical study, it was observed that children can experience a delay in weight gain and height increase while being treated with PEGASYS and another drug called COPEGUS. Catch-up in growth happens after treatment stops, however some children may not reach the height that they were expected to have before treatment. (PEGASYS is not authorized for use in children and adolescents under the age of 18 years.)

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and 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"/>	
	Weakness, loss of coordination and numbness, tingling or burning sensation in the arms or legs		<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 2-8°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, autoinjectors, 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. Keep this box out of the reach of children. When the box is full, follow your healthcare provider’s instructions for throwing it away. Placing used boxes in the household waste should be avoided.

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

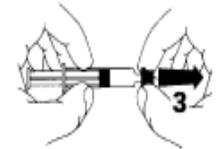
You may need to purchase these.

### Preparing the syringe and needle for injection

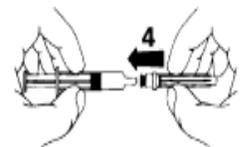
- Remove the protective cap that covers the back of the needle (1-2)



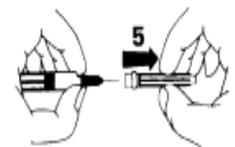
- Remove the rubber cap from the syringe (3). Do not touch the tip of the syringe.



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



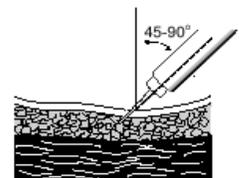
- Remove the needle guard from the syringe needle (5).



- 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).



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- 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.

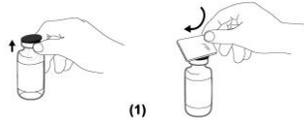
**Not included in the pack:**

- 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**

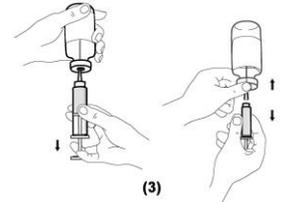
- Remove the protective cap from the PEGASYS vial (1).
- Clean the rubber top of the vial with an alcohol swab.
- Remove the needle and syringe from their packaging.
- Pull the syringe plunger back to the mark on the syringe barrel as instructed; this will pull air into the syringe barrel.
- Remove the needle guard without touching the needle and insert through the center of the stopper on the PEGASYS vial.



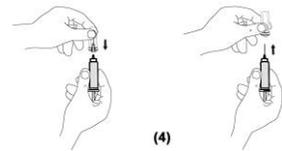
- Slowly inject all the air from the syringe into the air space above the solution. Do not inject air into the fluid (2).



- 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).

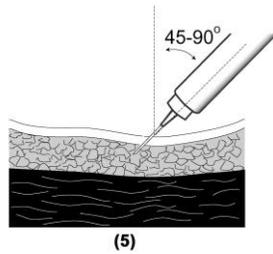


- Check for air bubbles in the syringe. If you see any bubbles, pull the plunger slightly back. To remove air bubbles from the syringe, hold the syringe with the needle pointing up. Tap the syringe gently to bring the bubbles to the top. Push the plunger up slowly to the correct dose. Replace the needle 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.

### **ProClick® Autoinjector:**

The following instructions will help you or your caregiver learn how to use the PEGASYS ProClick® autoinjector correctly. These instructions do not replace training from your healthcare provider. Your healthcare provider should show you how to prepare and use your autoinjector properly before you use it for the first time. Ask your healthcare provider any questions you may have. Do not attempt to administer an injection until you are sure that you understand how to use the autoinjector.

The ready to use autoinjector includes a post-injection needle shield that was designed to help prevent needle-stick injuries and keeps the needle non-visible. The autoinjector is for single use only and is then to be discarded.

### **Do not:**

- attempt to open the autoinjector or take it apart.
- expose to excessive forces or shock.
- use through clothing covering the skin.
- use if autoinjector appears to be damaged.
- use if medicine is cloudy, hazy, discoloured or has particles in it.
- shake the autoinjector.
- remove the blue cap if you are not ready to use it.
- re-use the autoinjector.
- push or pull the red needle-shield before, during or after use, as this is a safety device.

### **Getting ready:**

Wash your hands carefully before handling any of the items.

Collect the necessary items before beginning:

### **Included in the pack:**

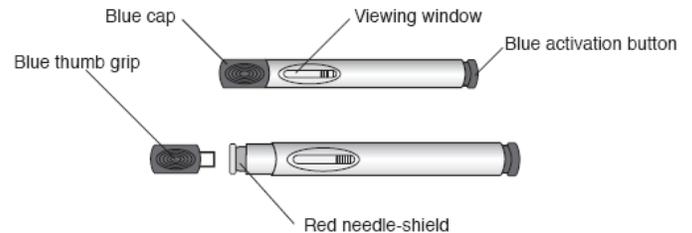
- a PEGASYS ProClick® autoinjector

### **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.

### **ProClick® Autoinjector parts:**



### **How to proceed:**

#### **1. Visually check the autoinjector**

Take the autoinjector out of the refrigerator. Visually examine the autoinjector, as well as the medicine through the viewing window. Do not shake. Do not remove the blue cap. If there is foam on the medicine, put the autoinjector back in the refrigerator and use at a later time.

Dispose of the autoinjector and use another if:

- the medicine is cloudy.
- the medicine contains particles.
- the medicine is any colour besides colourless to light yellow.
- any part of the autoinjector appears to be damaged.
- the expiration date has passed. You will find the expiration date on the box as well as on the label of the autoinjector itself.
- Contact your health care provider or pharmacist if the medicine in the autoinjector is cloudy or contains particles.

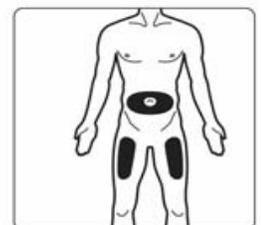
Keep the blue protective cap on the autoinjector until Step 4.

#### **2. Allow the autoinjector to adjust to room temperature**

Allow the refrigerated autoinjector to adjust to room temperature for about 20 minutes to warm up. Do not warm up autoinjector in any other way.

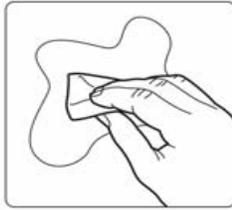
#### **3. Choose and prepare an injection site**

- Pick a place on your stomach or thigh (black areas in the picture). Avoid the 2 inch area around your belly-button (navel) and your waistline. You should use a different place each time you give yourself an injection. To minimize discomfort from injections, you may want to gently tap the area



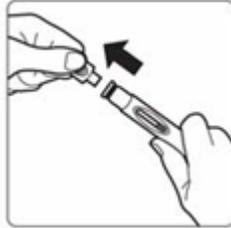
where you plan to give yourself an injection.

- Clean the injection site using an alcohol swab. Let the skin dry for 10 seconds. Be sure not to touch the cleaned area prior to injection.



#### 4. Remove blue cap

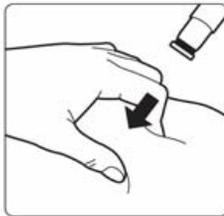
- Hold the autoinjector firmly with one hand and pull off the protective blue cap with the other hand.



NOTE: The cap contains a loose-fitting metal tube. Once the cap is removed, the autoinjector should be used immediately to avoid contamination. If it is not used within 5 minutes, the autoinjector should be disposed and a new autoinjector should be used. **Never re-attach the protective blue cap after removal.**

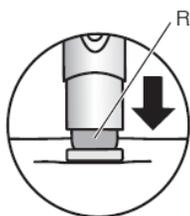
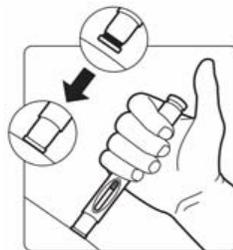
#### 5. Place the autoinjector on the injection site

- Hold the autoinjector comfortably in your hand. Pinch and hold a fold of skin at the injection site with your free hand, such that the needle-shield can rest on the skin-fold firmly and safely.
- Place autoinjector straight up and down at a right angle (90°) on the injection site.



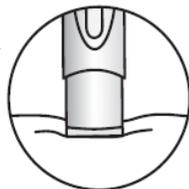
NOTE: Do not press the blue activation button yet.

- Press the autoinjector firmly against the skin until the red needle-shield is completely pushed in.
  - The autoinjector is now unlocked and ready for injection.



Red needle-shield

Press the autoinjector firmly against your skin until the red needle-shield is completely pushed in



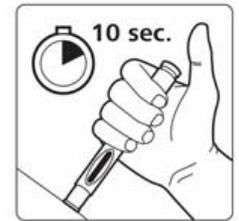
#### 6. Give Injection

- While holding autoinjector firmly in place, press the blue activation button with your thumb and **immediately release the blue button. Make sure to take your thumb off the blue activation button and do not press it again.**



- You should hear a "click" sound, telling you that the injection has started.
- The red indicator will move down in the viewing window during the injection.

- Keep the autoinjector pressed firmly on the skin for **10 seconds** for injection to complete.



- You might hear a second click as the blue activation button pops back up.
- The viewing window will now be completely red, confirming that the full dose has been delivered.

- Lift the autoinjector straight up (90° angle).

- The red needle-shield will automatically move out and lock to prevent needlestick injuries.



**CAUTION: If the viewing window is not completely filled by the red indicator:**

- the needle-shield may not have locked.
  - Do not touch the tip of the autoinjector, since needlestick injuries may occur.
- you may not have received an entire dose.
  - Do not try to use the autoinjector again.
  - Do not repeat the injection with another autoinjector.
  - **Call your healthcare provider for instructions.**

#### 7. After the injection

- Throw away used autoinjector and cap in a puncture-resistant disposable container immediately after use. Recapping is not required.
- Wipe the injection site with an alcohol swab.
- Wash your hands with soap and water.



- Throw away full containers according to directions provided by your healthcare provider.



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### **REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

### **MORE INFORMATION**

This brochure does not contain all known information about 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](http://www.rochecanada.com)

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\*Injection needle manufactured by Terumo Europe N. V.,  
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