

[Home](#) → [Drugs, Herbs and Supplements](#) → Peginterferon Alfa-2b (PEG-Intron)

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Peginterferon Alfa-2b (PEG-Intron)

pronounced as (peg in ter feer' on)

IMPORTANT WARNING:

Peginterferon alfa-2b may cause or worsen the following conditions that may be serious or cause death: infections; mental illness including depression, mood and behavior problems, or thoughts of hurting or killing yourself or others; starting to use street drugs again if you used them in the past; ischemic disorders (conditions in which there is poor blood supply to an area of the body) such as angina (chest pain), heart attack, or colitis (inflammation of the bowels); and autoimmune disorders (conditions in which the immune system attacks one or more parts of the body) that may affect the blood, joints, kidneys, liver, lungs, muscles, skin, or thyroid gland. Tell your doctor if you have an infection; or if you have or have ever had an autoimmune disease; atherosclerosis (narrowing of the blood vessels from fatty deposits); cancer; chest pain; colitis; diabetes; heart attack; high blood pressure; high cholesterol; HIV (human immunodeficiency virus) or AIDS (acquired immunodeficiency syndrome); irregular heartbeat; mental illness including depression, anxiety, or thinking about or trying to kill yourself; liver disease other than hepatitis C; or heart, kidney, lung or thyroid disease. Also tell your doctor if you drink or have ever drunk large amounts of alcohol, or if you use or have ever used street drugs or have overused prescription medications. If you experience any of the following symptoms, call your doctor immediately: bloody diarrhea or bowel movements; stomach pain, tenderness or swelling; chest pain; irregular heartbeat; changes in your mood or behavior; depression; irritability; anxiety; thoughts of killing or hurting yourself; hallucinating (seeing things or hearing voices that do not exist); frenzied or abnormally excited mood; loss of contact with reality; aggressive behavior; difficulty breathing; fever, chills, cough, sore throat, or other signs of infection; unusual bleeding or bruising; dark-colored urine; light colored bowel movements; extreme tiredness; yellowing of the skin or eyes; severe muscle or joint pain; or worsening of an autoimmune disease.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests to check your body's response to peginterferon alfa-2b.

Your doctor and pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with peginterferon alfa-2b and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>)

[<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of using peginterferon alfa-2b.

Use with ribavirin (Copegus, Rebetol):

You may take peginterferon alpha-2b with another medication called ribavirin (Copegus, Rebetol). Ribavirin may help peginterferon alpha-2b work better to treat your condition, but it may also cause serious side effects. The rest of this section presents the risks of taking ribavirin. If you are taking ribavirin, you should read this information carefully. Your doctor and pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with ribavirin and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Ribavirin may cause anemia (condition in which there is a decrease in the number of red blood cells). Tell your doctor if you have ever had a heart attack and if you have or have ever had high blood pressure, breathing problems, any condition that affects your blood such as sickle cell anemia (inherited condition in which the red blood cells are abnormally shaped and cannot bring oxygen to all parts of the body) or thalassemia (Mediterranean anemia; a condition in which the red blood cells do not contain enough of the substance needed to carry oxygen), or heart disease. If you experience any of the following symptoms, call your doctor immediately: excessive tiredness, pale skin, headache, dizziness, confusion, fast heartbeat, weakness, shortness of breath, or chest pain.

For female patients who are taking ribavirin:

Do not take ribavirin if you are pregnant or plan to become pregnant. You should not start taking ribavirin until a pregnancy test has shown that you are not pregnant. You must use two forms of birth control and be tested for pregnancy every month during your treatment and for 6 months afterward. Call your doctor immediately if you become pregnant during this time. Ribavirin may cause harm or death to the fetus.

For male patients who are taking ribavirin:

Do not take ribavirin if your partner is pregnant or plans to become pregnant. If you have a partner who can become pregnant, you should not start taking ribavirin until a pregnancy test shows that she is not pregnant. You must use two forms of birth control, including a condom with spermicide during your treatment and for 6 months afterward. Your partner must be tested for pregnancy every month during this time. Call your doctor immediately if your partner becomes pregnant. Ribavirin may cause harm or death to the fetus.

Why is this medication prescribed?

Peginterferon alfa-2b is used alone or in combination with ribavirin (a medication) to treat chronic (long-term) hepatitis C infection (swelling of the liver caused by a virus) in people who show signs of liver damage and who have not been treated with interferon alpha (medication similar to peginterferon alfa-2b) in the past. Peginterferon alfa-2b is in a class of medications called interferons. Peginterferon alfa-2b is a combination of interferon and polyethylene glycol, which helps the interferon stay active in your body for a longer period of time. Peginterferon alfa-2b works by decreasing the amount of hepatitis C virus (HCV) in the body. Peginterferon alfa-2b may not cure hepatitis C or prevent you from developing complications of hepatitis C such as cirrhosis (scarring) of the liver, liver failure, or liver cancer. Peginterferon alfa-2b may not prevent the spread of hepatitis C to other people.

How should this medicine be used?

Peginterferon alfa-2b comes as a powder in a vial and in a single dose injection pen to mix with liquid and inject subcutaneously (in the fatty layer just under the skin). It is usually injected once a week on the same day of the week, at or around the same time of day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Use peginterferon alfa-2b exactly as directed. Do not use more or less of this medication or use it more often or for a longer period of time than prescribed by your doctor.

Peginterferon alfa-2b controls hepatitis C but may not cure it. Continue to use peginterferon alfa-2b even if you feel well. Do not stop using peginterferon alfa-2b without talking to your doctor.

Only use the brand and type of interferon that your doctor prescribed. Do not use another brand of interferon or switch between peginterferon alfa-2b in vials and injection pens without talking to your doctor. If you switch to a different brand or type of interferon, your dose may need to be changed.

You can inject peginterferon alfa-2b yourself or have a friend or relative give you the injections. Before you use peginterferon alfa-2b for the first time, read the written instructions that come with it. Ask your doctor or pharmacist to show you or the person who will be injecting the medication how to inject it. If another person will be injecting the medication for you, be sure that he or she knows how to avoid accidental needle sticks to prevent the spread of HCV.

You can inject peginterferon alfa-2b anywhere on the outer part of your upper arms, your thighs, or your stomach except your navel (belly button) and waist. Do not inject into your stomach if you are very thin. Use a different spot for each injection. Do not inject peginterferon alfa-2b into an area where the skin is sore, red, bruised, scarred, irritated, or infected; has stretch marks or lumps; or is abnormal in any way.

Never reuse or share syringes, needles, injection pens, or vials of medication. Dispose of used needles, syringes, and injection pens in a puncture-resistant container. Talk to your doctor or pharmacist about how to dispose of the puncture-resistant container.

To use peginterferon alfa-2b injection pen, follow these steps:

1. Take the carton containing the injection pen out of the refrigerator and allow time for it to reach room temperature. Check the expiration date printed on the carton, and do not use the carton if the expiration date has passed. Check to be sure the carton contains the following supplies: injection pen, disposable needle, and alcohol swabs. You may also need an adhesive bandage and a piece of sterile gauze to use after your injection.

2. Look in the window of the injection pen and make sure that the cartridge holder chamber contains a white to off-white tablet that is whole or in pieces, or a powder.
3. Wash your hands thoroughly with soap and water, rinse, and towel dry. It is important to keep your work area, your hands, and the injection site clean to prevent infection.
4. Hold the injection pen upright (dose button down). You can use the bottom of the carton as a dosing tray to hold the pen in place. Press the two halves of the pen together firmly until you hear a click.
5. Wait several seconds for the powder to completely dissolve.
6. Gently turn the injection pen upside down twice to mix the solution. Do not shake the injection pen.
7. Turn the injection pen right side up and look through the window to see if the mixed solution is completely dissolved. If there is still foam, wait until it settles. It is normal to see some small bubbles near the top of the solution. If the solution is not clear or if you see particles, do not use it, and call your doctor or pharmacist.
8. Place the injection pen into the dose tray, with the dosing button on the bottom. Wipe the rubber cover of the injection pen with an alcohol pad.
9. Remove the protective paper tab from the injection needle. Keep the injection pen upright in the dose tray and gently push the injection needle straight onto the injection pen. Screw the needle securely in place. You may see some liquid trickle out from under the cap for a few seconds. Wait until this stops before going to the next step.
10. Remove the injection pen from the dose tray. Hold the pen firmly and pull the dosing button out as far as it will go, until you see the dark bands (lines) below the dosing button. Be careful not to push the dosing button in until you are ready to inject the medication.
11. Turn the dosing button until the number that matches your prescribed dose is lined up with the dosing tab. If you are not sure which number matches your dose, stop, and call your doctor or pharmacist before you inject any medication.
12. Choose your injection spot and clean the skin in the area with an alcohol pad. Wait for the area to dry.
13. Remove the outer cap from the injection pen needle. There may be liquid around the inner needle cap. This is normal. Once the skin at the injection spot is dry, pull off the inner needle cap. Be careful not to touch the needle to anything.
14. Hold the injection pen with your fingers wrapped around the pen body barrel and your thumb on the dosing button.
15. With your other hand, pinch up the skin in the area you have cleaned for the injection. Insert the needle into the pinched skin at an angle of 45 to 90 degrees.
16. Inject the medication by pressing the dosing button down slowly and firmly until you can't push it any further. Keep your thumb pressed down on the dosing button for an additional 5 seconds to make sure you get the complete dose.
17. Pull the injection pen needle out of your skin at the same angle you put it into your skin.
18. Gently press the injection spot with a small bandage or sterile gauze if necessary for a few seconds, but do not massage or rub the injection site.
19. If there is bleeding, cover the injection spot with an adhesive bandage.
20. Dispose of the injection pen with the needle still attached in a puncture-proof container. Do not recap the needle.

21. Two hours after the injection, check the injection spot for redness, swelling, or tenderness. If you have a skin reaction and it doesn't clear up in a few days or it worsens, call your doctor or nurse.

To use peginterferon alfa-2b in vials, follow these steps:

1. Wash your hands thoroughly with soap and water, rinse, and towel dry.
2. Check the expiration date printed on the carton of peginterferon alfa-2b and do not use the carton if the expiration date has passed. Take the following supplies out of the carton and place them on a clean work area: a vial of peginterferon alfa-2b, a vial of sterile water for injection (diluent), two syringes with needles attached, and alcohol pads.
3. Remove the protective wrapper from one of the syringes.
4. Flip off the protective caps from the tops of the peginterferon alfa-2b vial and the diluent vial. Clean the rubber stoppers on the tops of both vials with an alcohol pad.
5. Remove the protective needle cap and fill the syringe with air by pulling the plunger back to the 0.7 mL mark on the barrel.
6. Hold the sterile water vial upright without touching the cleaned top with your hands.
7. Insert the syringe needle through the rubber stopper and press down on the plunger to inject the air from the syringe into the vial.
8. Turn the vial upside down with the syringe still attached, and make sure the tip of the needle is in the liquid. Withdraw 0.7 mL of sterile water by pulling the syringe plunger back to exactly the 0.7 mL mark.
9. Remove the needle from the diluent vial by pulling it straight up out of the rubber stopper. Do not touch the needle to anything.
10. Insert the needle through the rubber stopper of the peginterferon alfa-2b vial, and place the needle tip against the glass wall of the vial.
11. Slowly inject the 0.7 mL of sterile water so that it runs down the glass inside the vial. Do not aim the stream of sterile water at the white powder in the bottom of the vial.
12. Remove the needle from the vial by pulling the syringe straight out of the rubber stopper. Hold the safety sleeve tightly and pull it over the needle until you hear a click and the green stripe on the sleeve covers the red stripe on the needle. Dispose of the syringe in a puncture-proof container.
13. Gently swirl the vial in a circular motion until the powder is completely dissolved. If the solution is cold, roll the vial gently in your hands to warm it.
14. If air bubbles have formed, wait until the solution has settled and all the bubbles have risen to the top of the solution and disappeared before going on to the next step.
15. Look carefully at the liquid in the bottle. Do not inject the liquid unless it is clear, colorless, and does not contain particles.
16. Clean the rubber stopper on the vial of peginterferon alfa-2b again with another alcohol pad.
17. Remove the protective packaging from the second syringe. Remove the protective cap from the needle of the syringe.
18. Fill the syringe with air by pulling the plunger back to the mL mark that matches your prescribed dose. If you are not sure which mark on the syringe matches your dose, stop and call your doctor or pharmacist before you inject the medication.

19. Hold the vial of peginterferon alfa-2b upright without touching the cleaned top of the vial with your hands.
20. Insert the syringe needle into the peginterferon alfa-2b solution vial, and press down on the plunger to inject the air into the vial.
21. Hold the vial and syringe and slowly turn the vial upside down with the needle still inside the vial. Keep the tip of the needle in the solution.
22. Slowly pull the syringe plunger back to the correct mark to withdraw the amount of peginterferon alfa-2b that your doctor prescribed.
23. Pull the syringe straight out of the vial. Do not touch the needle to anything.
24. Check for air bubbles in the syringe. If you see any bubbles, hold the syringe with the needle pointing up and gently tap the syringe until the bubbles rise. Then, carefully push the syringe plunger in slowly until the bubbles disappear, without pushing any of the solution out of the syringe.
25. Choose an injection spot and clean the skin in the area with an alcohol pad. Wait for the area to dry.
26. Remove the protective cap from the needle. Make sure the safety sleeve of the syringe is pushed firmly against the rim of the syringe so that the needle is fully exposed.
27. Pinch up a 2-inch (5-centimeter) fold of loose skin at the injection spot. With your other hand, pick up the syringe and hold it like a pencil with the point (bevel) of the needle facing up. Push the needle approximately 1/4 inch (0.6 centimeters) into the pinched skin at a 45- to 90-degree angle, using a quick, dart-like thrust.
28. Let the pinched skin loose and use that hand to help hold the syringe barrel.
29. Pull the plunger of the syringe back very slightly. If blood comes into the syringe, the needle has entered a blood vessel. Do not inject. Pull the needle out at the same angle you put it into the skin, and dispose of the syringe in a puncture-proof container. Repeat the steps above to prepare a new dose using a new syringe and a new vial. If no blood comes into the syringe, inject the medication by gently pressing the plunger all the way down the syringe barrel.
30. Hold an alcohol pad near the needle and pull the needle straight out of the skin. Press the alcohol pad over the injection site for several seconds. Do not rub or massage the injection site. If there is bleeding, cover it with a bandage.
31. Cover the syringe with the safety sleeve the same way that you covered the first syringe. (See Step 12 above.) Dispose of the syringe and the needle in a puncture-proof container.
32. Two hours after the injection, check the injection spot for redness, swelling, or tenderness. If you have a skin reaction and it doesn't clear up in a few days or it worsens, call your doctor or nurse.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking peginterferon alfa-2b,

- tell your doctor and pharmacist if you are allergic to peginterferon alfa-2b, other alpha interferons, any other medications, or polyethylene glycol (PEG). Ask your doctor if you are not sure if a medication you are allergic to is an alpha interferon.

- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and methadone (Dolophine, Methadose). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor or pharmacist if you have ever had an organ transplant (surgery to replace a part of the body) or if you have or have ever had any of the conditions mentioned in the IMPORTANT WARNING section or any of the following: sleep problems, or problems with your eyes or pancreas.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. Peginterferon alfa-2b may harm the fetus or cause you to miscarry (lose your baby). Talk to your doctor about using birth control while you are taking this medication. You should not breast-feed while you are taking this medication.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking peginterferon alfa-2b.
- you should know that peginterferon alfa-2b may make you drowsy, dizzy, or confused. Do not drive a car or operate machinery until you know how this medication affects you.
- you should know that you may experience flu-like symptoms such as fever, chills, muscle aches, and joint pain during your treatment with peginterferon alfa-2b. If these symptoms are bothersome, ask your doctor if you should take an over-the-counter pain and fever reducer before you inject each dose of peginterferon alfa-2b. You may want to inject peginterferon alfa-2b at bedtime so that you can sleep through the symptoms.
- plan to get plenty of rest and regular light exercise during your treatment. Talk to your doctor about safe ways to exercise during your treatment.

What special dietary instructions should I follow?

Drink at least 10 full glasses of water or clear juices without caffeine or alcohol every day during your treatment with peginterferon alfa-2b. Be especially careful to drink enough fluid during the first weeks of your treatment.

Be sure to eat well during your treatment. If you have an upset stomach or don't have an appetite, eat healthy snacks or several smaller meals throughout the day.

What should I do if I forget a dose?

If you remember the missed dose no later than the day after you were scheduled to inject it, inject the missed dose as soon as you remember it. Then inject your next dose on your regularly scheduled day the following week. If you do not remember the missed dose until several days have passed, check with your doctor about what to do. Do not double the next dose or take more than one dose a week without talking to your doctor.

What side effects can this medication cause?

Peginterferon alfa-2b may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- bruising, pain, redness, swelling, itching, or irritation in a place where you injected peginterferon alfa-2b

- nausea
- vomiting
- loss of appetite
- change in the way things taste
- diarrhea
- constipation
- heartburn
- weight loss
- headache
- dizziness
- confusion
- hair loss or thinning
- itching
- difficulty concentrating
- feeling cold or hot all the time
- changes to your skin
- dry mouth
- sweating
- flushing
- runny nose
- difficulty falling asleep or staying asleep

Some side effects can be serious. The following symptoms are uncommon, but if you experience any of them, or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- rash
- hives
- difficulty swallowing
- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- hoarseness
- fast heartbeat
- pale skin
- lower back pain

Peginterferon alfa-2b may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store peginterferon alfa-2b injection pens in the refrigerator, and do not expose them to heat. Store vials of peginterferon alfa-2b powder at room temperature and away from excess heat and moisture (not in the bathroom). It is best to inject peginterferon alfa-2b solution in vials or injection pens immediately after mixing. If necessary, vials or injection pens containing prepared peginterferon alfa-2b solution may be stored in the refrigerator for up to 24 hours. Do not freeze peginterferon alfa-2b.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

If the victim has not collapsed, call the doctor who prescribed this medication. The doctor may want to examine the victim more closely and perform laboratory tests.

What other information should I know?

Do not let anyone else use your medication or any of your injection supplies. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary

supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- PEG-Intron®

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