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Peginterferon Alfa-2a Injection

pronounced as (peg in ter feer' on)

IMPORTANT WARNING:

Peginterferon alfa-2a may cause or worsen the following conditions, which may be serious or cause death: infections; mental illness including depression, mood and behavior problems, or thoughts of hurting or killing yourself; 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, stroke, 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 B or 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; weakness; loss of coordination; numbness; 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; coughing up yellow or pink mucus; burning or pain when urinating, or urinating more often; 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-2a.

Your doctor and pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with peginterferon alfa-2a 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-2a.

Why is this medication prescribed?

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

How should this medicine be used?

Peginterferon alfa-2a comes as a solution (liquid) in a vial, a prefilled syringe, and a disposable autoinjector to inject subcutaneously (into the fatty layer just under the skin). It is usually injected once a week, on the same day of the week, and at 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-2a exactly as directed. Do not use more or less of this medication or use it more often than prescribed by your doctor.

Your doctor will probably start you on an average dose of peginterferon alfa-2a. Your doctor may decrease your dose if you experience serious side effects of the medication. Be sure to tell your doctor how you are feeling during your treatment and ask your doctor or pharmacist if you have questions about the amount of medication you should take.

Continue to use peginterferon alfa-2a even if you feel well. Do not stop using peginterferon alfa-2a 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-2a in vials, prefilled syringes, and disposable autoinjectors 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-2a yourself or have a friend or relative give you the injections. Before you use peginterferon alfa-2a for the first time, you and the person who will be giving the injections should read the manufacturer's information for the patient that comes 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 needlesticks to prevent the spread of hepatitis.

You can inject peginterferon alfa-2a anywhere on your stomach or thighs, except your navel (belly button) and waistline. Use a different spot for each injection. Do not use the same injection spot two times in a row. Do not inject peginterferon alfa-2a into an area where the skin is sore, red, bruised, scarred, infected, or abnormal in any way.

If you do not receive the full prescribed dose because of a problem (such as leakage around the injection site), call your doctor.

Never reuse syringes, needles, or vials of peginterferon alfa-2a. Dispose of used needles and syringes in a puncture-resistant container. Talk to your doctor or pharmacist about how to dispose of the puncture-resistant container.

Before you use peginterferon alfa-2a, look at the solution in the vial, prefilled syringe, or autoinjector closely. Do not shake vials, syringes, or autoinjectors containing peginterferon alfa-2a. The medication should be clear and free of floating particles. Check the vial or syringe to make sure there are no leaks and check the expiration date. Do not use the solution if it is expired, discolored, cloudy, contains particles, or is in a leaky vial or syringe. Use a new solution, and show the damaged or expired one to your doctor or pharmacist.

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 using peginterferon alfa-2a,

- tell your doctor and pharmacist if you are allergic to peginterferon alfa-2a, other alpha interferons, any other medications, benzyl alcohol, 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 if you have ever received interferon alfa injection for treating hepatitis C infection.
- 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 any of the following: certain medications for HIV or AIDS such as abacavir (Ziagen, in Epzicom, in Trizivir), didanosine (ddl or Videx), emtricitabine (Emtriva, in Truvada), lamivudine (Epivir, in Combivir, in Epzicom, in Trizivir), stavudine (Zerit), tenofovir (Viread, in Truvada), zalcitabine (HIVID), and zidovudine (Retrovir, in Combivir, in Trizivir); methadone (Dolophine, Methadose); mexiletine (Mexitil); naproxen (Aleve, Anaprox, Naprosyn, others); riluzole (Rilutek); tacrine (Cognex); telbivudine (Tyzeka); and theophylline (TheoDur, others). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with peginterferon alfa-2a, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor or pharmacist if you have ever had an organ transplant (surgery to replace an organ in the body). Also tell your doctor if you have or have ever had any of the conditions mentioned in the

IMPORTANT WARNING section or any of the following: anemia (red blood cells do not bring enough oxygen to other parts of the body), or problems with your eyes or pancreas.

- tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding. Peginterferon alfa-2a 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 breastfeed 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-2a.
- you should know that peginterferon alfa-2a may make you dizzy, confused, or drowsy. Do not drive a car or operate machinery until you know how this medication affects you.
- do not drink alcohol while you are taking peginterferon alfa-2a. Alcohol can make your liver disease worse.
- you should know that you may experience flu-like symptoms such as headache, fever, chills, tiredness, muscle aches, and joint pain during your treatment with peginterferon alfa-2a. 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-2a. You may want to inject peginterferon alfa-2a at bedtime so that you can sleep through the symptoms.

What special dietary instructions should I follow?

Drink plenty of fluids while you are taking this medication.

What should I do if I forget a dose?

If you remember the missed dose no longer than 2 days 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 more than 2 days have passed since the day you were scheduled to inject the medication, ask your doctor or pharmacist what you should do. Do not use a double dose or use more than one dose in 1 week to make up for a missed dose.

What side effects can this medication cause?

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

- bruising, pain, redness, swelling, or irritation in the place you injected peginterferon alfa-2a
- upset stomach
- vomiting
- heartburn
- dry mouth
- loss of appetite
- weight loss
- diarrhea
- dry or itchy skin

- hair loss
- difficulty falling asleep or staying asleep
- tiredness
- weakness
- difficulty concentrating or remembering
- sweating
- dizziness

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 or the SPECIAL PRECAUTIONS section, call your doctor immediately:

- blurred vision ,vision changes, or loss of vision
- lower back pain
- rash
- hives
- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- difficulty swallowing
- hoarseness

Peginterferon alfa-2a 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 it in the refrigerator, but do not freeze it. Do not leave peginterferon alfa-2a outside of the refrigerator for more than 24 hours (1 day). Keep peginterferon alfa-2a away from light.

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 order lab tests.

Symptoms of overdose may include the following:

- tiredness
- unusual bleeding or bruising
- fever, sore throat, chills, cough, or other signs of infection

What other information should I know?

Do not let anyone else use your medication. 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

- Pegasys®

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