

Patient Education

PEGINTERFERON ALFA 2A - INJECTABLE

IMPORTANT NOTE: This is a summary and does not contain all possible information about this product. For complete information about this product or your specific health needs, ask your health care professional. Always seek the advice of your health care professional if you have any questions about this product or your medical condition. This information is not intended as individual medical advice and does not substitute for the knowledge and judgment of your health care professional. This information does not contain any assurances that this product is safe, effective, or appropriate for you.

PEGINTERFERON ALFA 2A - INJECTABLE

(peg-in-ter-FEER-on alfa)

COMMON BRAND NAME(S): Pegasys

WARNING: This medication may cause or worsen some serious medical conditions, including psychiatric conditions (e.g., depression); immune disorders (autoimmune conditions such as rheumatoid arthritis or lupus); circulation problems (e.g., cardiovascular disease); or infections (bone marrow suppression). Seek immediate medical attention if you develop any serious symptoms or side effects (see Side Effects section). These conditions occur infrequently, but some may be fatal.

This medicine is frequently combined with ribavirin. Ribavirin may cause harm to an unborn baby or death. Women must avoid pregnancy while they or their male partners are using ribavirin. Ribavirin may cause a blood disorder (hemolytic anemia), which can worsen heart disease. Ribavirin is a potential cancer-causing agent.

USES:

Peginterferon alfa-2a is used alone or in combination with ribavirin to treat chronic hepatitis C, a viral infection of the liver.

This medication reduces the amount of hepatitis C virus in the body and helps the body's immune system fight the infection. It is not known if peginterferon can cure hepatitis C virus infections (permanently eliminate the virus from your body). It is also not known if this drug can prevent you from passing the virus to others. Practice "safe sex" (including the use of latex condoms) to lower the risk of passing the virus to others.

HOW TO USE:

Read and learn all preparation and usage instructions in the Medication Guide provided by your pharmacist before you start using peginterferon alfa 2A and each time you get a refill. If you have any questions regarding the information, consult your doctor or pharmacist.

Inject this medication under the skin (subcutaneously) on your stomach or thigh, once weekly or as directed by your doctor. Do not inject near the belly button or at the waistline. Use a different place each time you give yourself an injection. The dose should be given at about the same time on the same day each week. The dosage is based on your medical condition and response to therapy.

Drink plenty of fluids while you are taking this medication unless your doctor directs you otherwise. Additional administration guidelines may be available in the Medication Guide.

Before using, check this product visually for particles or discoloration. If either is present, do not use the liquid. Do not shake this medication. Doing so may decrease the effectiveness of this medication.

Learn how to store and discard needles and medical supplies safely. Consult your pharmacist.

SIDE EFFECTS:

Flu-like symptoms (e.g., fever, chills, muscle aches, fatigue, headache, joint pain, nausea, stomach pain, cough) may occur. If instructed to do so, you may take pain/fever-reducing medications (e.g., acetaminophen, ibuprofen) to help with these symptoms. Dry mouth, loss of appetite, weight loss, trouble sleeping, diarrhea, dry skin, or redness/swelling at the injection site may also occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

Temporary hair loss may occur. Normal hair growth should return after treatment has ended.

Remember that your doctor has prescribed this medication because the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor immediately if any of these unlikely but serious side effects occur: persistent sore throat or fever, easy or unusual bleeding/bruising, unusually severe fatigue.

Tell your doctor immediately if any of these rare but very serious side effects occur: chest pain, unusually slow/fast/pounding heartbeat, vision changes, seizures, change in the amount of urine, weakness on one side of the body, severe stomach pain with nausea/vomiting, black/tarry stools, vomit that looks like coffee grounds, yellowing eyes or skin, dark urine, increased thirst, increased urination, bloody diarrhea.

This drug may infrequently cause severe mental/mood changes (e.g., suicidal thoughts or severe depression). If you notice these symptoms, stop your treatment with peginterferon and seek immediate medical attention.

A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing.

If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS:

Before taking peginterferon alfa-2a, tell your doctor or pharmacist if you are allergic to it; or to polyethylene glycol (PEG); or if you have any other allergies.

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: other severe liver disease (e.g., autoimmune hepatitis, hepatic decompensation).

Before taking this medication, tell your doctor or pharmacist your medical history, especially of: psychiatric conditions (e.g., depression), low blood counts (e.g., red cells, white cells, or platelets), heart disease, thyroid problems, autoimmune disease (e.g.,

rheumatoid arthritis, lupus, psoriasis), eye problems, kidney disease, lung disease (e.g., COPD, asthma, pneumonia), history of cancer, intestinal disease (e.g., colitis), pancreatitis, history of drug/alcohol abuse, diabetes, other infections (e.g., HIV, hepatitis B, chickenpox), high blood triglyceride levels, history of organ transplant, liver problems (other than hepatitis C).

Do not have immunizations/vaccinations without the consent of your doctor.

Use caution with sharp objects like safety razors or nail cutters and avoid activities such as contact sports to lower the chance of getting cut, bruised, or injured.

This drug may make you drowsy or dizzy; use caution engaging in activities requiring alertness such as driving or using machinery.

This medicine may cause stomach bleeding. Daily use of alcohol and this medicine may increase your risk for stomach bleeding.

A preservative (benzyl alcohol) which may be found in this product can infrequently cause serious problems (sometimes death) if given in large amounts (more than 100 milligrams per kilogram daily) to an infant during the first months of life (neonatal period). The risk is also greater with low birth weight infants. Symptoms include sudden gasping, low blood pressure, or a very slow heartbeat. Report these symptoms to the doctor immediately should they occur. If possible, a preservative-free product should be used when treating neonates.

Caution is advised when using this drug in the elderly because they may be more sensitive to its effects.

This medication is not recommended for use during pregnancy because of possible serious harm to the unborn baby. Consult your doctor for more details and to discuss reliable forms of birth control. It is recommended that men and women use birth control measures while being treated with this medication and for the 6 months after treatment has stopped. If you become pregnant or think you may be pregnant, inform your doctor immediately.

It is not known whether this drug passes into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first.

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: theophylline.

OVERDOSE:

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

NOTES:

Do not share this medication with others.

Laboratory and/or medical tests (e.g., blood tests, thyroid tests, virus levels, kidney function tests, triglyceride levels) should be performed periodically to monitor your progress or check for side effects. Depending on your medical history, other tests (e.g., EKG) may be needed. Consult your doctor for more details.

You may need an eye exam before using this medication. If you have an eye disease or have a condition that places you at greater risk for eye disease (e.g., diabetes), you should have periodic eye exams while using this drug.

Do not change brands of interferon without checking with your doctor or pharmacist. Other interferons may not have the same effects on your disease.

MISSED DOSE:

If you miss a dose and you remember within 2 days of when you should have taken the medication, give the injection as soon as remembered. Take your next dose on the day you usually take it. If more than 2 days have passed since your missed dose, contact your doctor or pharmacist to establish a new dosing schedule.

STORAGE:

Store in the refrigerator between 36-46 degrees F (2-8 degrees C). This medication should not be left outside the refrigerator for more than 24 hours. Do not freeze. Protect from light. Each vial or prefilled syringe can be used only once; discard any unused portion. Keep this medication and any discarded syringes/needles away from children and pets.

MEDICAL ALERT: Your condition can cause complications in a medical emergency. For enrollment information call MedicAlert at 1-800-854- 1166 (USA) or 1-800-668-1507 (Canada).