

MEDICATION GUIDE
PEGINTRON[®] (peg-In-tron)
(Peginterferon alfa-2b)
for injection, for subcutaneous use

Important: When taking PEGINTRON in combination with ribavirin, you should also read the ribavirin Medication Guide. If your healthcare provider also prescribes an approved hepatitis C virus (HCV) medicine for you, also read the Medication Guide that comes with that medicine.

What is the most important information I should know about PEGINTRON?

PEGINTRON can cause serious side effects that:

- may cause death, or
- may worsen certain serious diseases that you may already have.

Tell your healthcare provider right away if you have any of the symptoms listed below while taking PEGINTRON. If symptoms get worse, or become severe and continue, your healthcare provider may tell you to stop taking PEGINTRON permanently. In many, but not all, people, these symptoms go away after they stop taking PEGINTRON.

Mental health problems, including suicide. PEGINTRON may cause you to develop mood or behavior problems that may get worse during treatment with PEGINTRON or after your last dose, including:

- irritability (getting upset easily)
- depression (feeling low, feeling bad about yourself, or feeling hopeless)
- acting aggressive, being angry or violent
- thoughts of hurting yourself or others, or suicide
- former drug addicts may fall back into drug addiction or overdose

If you have these symptoms, your healthcare provider should carefully monitor you during treatment with PEGINTRON and for 6 months after your last dose.

Heart problems. Some people who take PEGINTRON may get heart problems, including:

- low blood pressure
- fast heart rate or abnormal heart beat
- trouble breathing or chest pain
- heart attacks or heart muscle problems (cardiomyopathy)

Stroke or symptoms of a stroke. Symptoms may include weakness, loss of coordination, and numbness. Stroke or symptoms of a stroke may happen in people who have some risk factors **or** no known risk factors for a stroke.

New or worsening autoimmune problems. Some people taking PEGINTRON develop autoimmune problems (a condition where the body's immune cells attack other cells or organs in the body), including rheumatoid arthritis, systemic lupus erythematosus, and psoriasis. In some people who already have an autoimmune problem, it may get worse during your treatment with PEGINTRON.

Infections. Some people who take PEGINTRON may get an infection. Symptoms may include:

- fever
- chills
- bloody diarrhea
- burning or pain with urination
- urinating often

- coughing up mucus (phlegm) that is discolored (for example, yellow or pink)

When taking PEGINTRON in combination with ribavirin you should also read the ribavirin Medication Guide for important information, including information about pregnancy and the fast breakdown of red blood cells (hemolytic anemia).

During treatment with PEGINTRON, you should see a healthcare provider regularly for check-ups and blood tests to make sure that your treatment is working, and to check for side effects.

What is PEGINTRON?

PEGINTRON is a prescription medicine that is used:

- with ribavirin and an approved hepatitis C virus (HCV) protease inhibitor to treat chronic (lasting a long time) hepatitis C infection in adults.
- with ribavirin to treat chronic (lasting a long time) hepatitis C infection in people 3 years and older with stable liver problems.
- alone, sometimes to treat adults who have chronic (lasting a long time) hepatitis C infection with stable liver problems and who cannot take ribavirin.

People with hepatitis C have the virus in their blood and in their liver. PEGINTRON reduces the amount of virus in the body and helps the body's immune system fight the virus. Ribavirin is a drug that helps to fight the viral infection but does not work when used by itself to treat chronic hepatitis C.

It is not known if PEGINTRON use for longer than 1 year is safe and will work.

It is not known if PEGINTRON use in children younger than 3 years old is safe and will work.

Who should not take PEGINTRON?

Do not take PEGINTRON:

- if you have had a serious allergic reaction to another alpha interferon or to any of the ingredients in PEGINTRON. See the end of this Medication Guide for a complete list of ingredients in PEGINTRON. Ask your healthcare provider if you are not sure.
- if you have certain types of hepatitis (autoimmune hepatitis).
- if you have certain other liver problems.
- in combination with ribavirin:
 - if you are a female who is pregnant or plans to become pregnant
 - if you are a male with a female partner who is pregnant.

Ribavirin may cause birth defects and death of an unborn baby.

When taking PEGINTRON in combination with ribavirin you should also read the Medication Guide for ribavirin for important pregnancy information.

Talk to your healthcare provider before taking PEGINTRON if you have any of these conditions.

What should I tell my healthcare provider before taking PEGINTRON?

Before you take PEGINTRON, see “What is the most important information I should know about PEGINTRON?”, and tell your healthcare provider if you:

- are being treated for a mental illness or had treatment in the past for any mental illness, including depression and thoughts of hurting yourself or others
- have or ever had any problems with your heart, including heart attack or high blood pressure
- have any kind of autoimmune disease (where the body’s immune system attacks the body’s own cells), such as psoriasis, systemic lupus erythematosus, rheumatoid arthritis
- have or ever had bleeding problems or a blood clot
- have or ever had low blood cell counts
- have ever been addicted to drugs or alcohol
- have cirrhosis or other liver disease (other than hepatitis C infection)
- have or had lung disease such as chronic obstructive pulmonary disease (COPD)
- have thyroid problems
- have diabetes
- have colitis (inflammation of your intestine)
- have a condition that suppresses your immune system, such as cancer
- have hepatitis B infection
- have HIV infection
- have kidney problems
- have high blood triglyceride levels (fat in your blood)
- have an organ transplant and are taking medicine that keeps your body from rejecting your transplant (suppresses your immune system)
- have any other medical problems
- are pregnant or plan to become pregnant.
 - PEGINTRON can harm your unborn baby.
 - Your healthcare provider should do a pregnancy test to see if you are pregnant before you begin taking PEGINTRON.
 - Avoid becoming pregnant during treatment with PEGINTRON. You should use effective birth control during treatment and for at least 10 days after your final dose of PEGINTRON.
 - **Call your healthcare provider right away if you become pregnant during treatment with PEGINTRON.**
 - **See “Who should not take PEGINTRON?” When taking PEGINTRON in combination with ribavirin you should also read the ribavirin Medication Guide for important pregnancy information.**
- are breastfeeding or plan to breastfeed. It is not known if PEGINTRON passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take PEGINTRON.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. PEGINTRON and certain other medicines may affect each other and cause side effects.

Especially tell your healthcare provider if you take the anti-hepatitis B medicine telbivudine (Tyzeka).

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take PEGINTRON?

- Take PEGINTRON exactly as your healthcare provider tells you to. Your healthcare provider will tell you how much PEGINTRON to take and when to take it. Do not take more than your prescribed dose.
- Take your prescribed dose of PEGINTRON every week, on the same day of each week and at the same time.
- PEGINTRON is given as an injection under your skin (subcutaneous injection). Your healthcare provider should show you how to prepare and measure your dose of PEGINTRON, and how to inject yourself before you use PEGINTRON for the first time.
- You should not inject PEGINTRON until your healthcare provider has shown you how to use PEGINTRON the right way.
- PEGINTRON comes as a:
 - powder in a single-dose vial
 - single-dose REDIPEN

Your healthcare provider will prescribe the PEGINTRON that is right for you. See the Instructions for Use that comes with your PEGINTRON for detailed instructions for preparing and injecting a dose of PEGINTRON.

- If you miss a dose of PEGINTRON, take the missed dose as soon as possible during the same day or the next day, then continue on your regular dosing schedule. If several days go by after you miss a dose, check with your healthcare provider about what to do.
- Do not inject more than 1 dose of PEGINTRON in one week without talking to your healthcare provider.
- If you take too much PEGINTRON, call your healthcare provider right away. Your healthcare provider may examine you more closely and do blood tests.
- Your healthcare provider should do blood tests before you start PEGINTRON, and regularly during treatment to see how well the treatment is working and to check you for side effects.

What are the possible side effects of PEGINTRON?

PEGINTRON may cause serious side effects including:

See "What is the most important information I should know about PEGINTRON?"

- **Serious eye problems.** PEGINTRON may cause eye problems that may lead to vision loss or blindness. You should have an eye exam before you start taking PEGINTRON. If you have eye problems or have had them in the past, you may need eye exams while you are taking PEGINTRON. Tell your healthcare provider or eye doctor right away if you have any vision changes while taking PEGINTRON.
- **Blood problems.** PEGINTRON can affect your bone marrow and cause low white blood cell and platelet counts. In some people, these blood counts may fall to dangerously low levels. If your blood counts become very low, you can get infections, and problems with bleeding and bruising.
- **Swelling of your pancreas (pancreatitis) or intestines (colitis).** Symptoms may include:
 - severe stomach area (abdomen) pain
 - severe back pain
 - nausea and vomiting
 - bloody diarrhea
 - fever
- **Lung problems including:**
 - trouble breathing
 - pneumonia
 - inflammation of lung tissue
 - new or worse high blood pressure of the lungs (pulmonary hypertension). This can be severe and may lead to death.

You may need to have a chest X-ray or other tests if you develop fever, cough, shortness of breath or other symptoms of a lung problem during treatment with PEGINTRON.

- **Severe liver problems, or worsening of liver problems, including liver failure and death.** Symptoms may include:
 - nausea
 - loss of appetite
 - tiredness
 - diarrhea
 - yellowing of your skin or the white part of your eyes
 - bleeding more easily than normal
 - swelling of your stomach area (abdomen)
 - confusion
 - sleepiness
 - you cannot be awakened (coma)
- **Thyroid problems.** Some people develop changes in their thyroid function. Symptoms of thyroid changes include:
 - problems concentrating
 - feeling cold or hot all of the time
 - weight changes
 - skin changes
- **Blood sugar problems.** Some people may develop high blood sugar or diabetes. If you have high blood sugar or diabetes that is not controlled before starting PEGINTRON, talk to your healthcare provider before you take PEGINTRON. If you develop high blood sugar or diabetes while taking PEGINTRON, your healthcare provider may tell you to stop PEGINTRON and prescribe a different medicine for you. Symptoms of high blood sugar or diabetes may include:
 - increased thirst
 - tiredness

- urinating more often than normal
- increased appetite
- weight loss
- your breath smells like fruit
- **Serious allergic reactions and skin reactions.** Get medical help right away if you get any of the following symptoms:
 - itching
 - swelling of the face, eyes, lips, tongue, or throat
 - trouble breathing
 - anxiousness
 - chest pain
 - feeling faint
 - skin rash, hives, sores in your mouth, or your skin blisters and peels
- **Growth problems in children.** Weight loss and slowed growth are common in children during combination treatment with PEGINTRON and ribavirin. Most children will go through a growth spurt and gain weight after treatment stops. Some children may not reach the height that they were expected to have before treatment. Talk to your healthcare provider if you are concerned about your child's growth during treatment with PEGINTRON and ribavirin.
- **Nerve problems.** People who take PEGINTRON or other alpha interferon products with telbivudine (Tyzeka) can develop nerve problems such as continuing numbness, tingling, or burning sensation in the arms or legs (peripheral neuropathy). Call your healthcare provider if you have any of these symptoms.
- **Dental and gum problems.** Brush your teeth well 2 times each day. Get regular dental exams. If you vomit at any time during treatment with PEGINTRON, rinse your mouth out well.

Tell your healthcare provider right away if you have any of the symptoms listed above.

The most common side effects of PEGINTRON include:

- **Flu-like symptoms.** Symptoms may include: headache, muscle aches, tiredness, and fever. Some of these symptoms may be decreased by injecting your PEGINTRON dose at bedtime. Talk to your healthcare provider about which over-the-counter medicines you can take to help prevent or decrease some of these symptoms.
- **Tiredness.** Many people become very tired during treatment with PEGINTRON.
- **Appetite problems.** Nausea, loss of appetite, and weight loss can happen with PEGINTRON.
- **Skin reactions.** Redness, swelling, and itching are common at the site of injection.
- **Hair thinning.**

PEGINTRON may cause fertility problems in females, which may affect the ability to have children. Talk to your healthcare provider if you have concerns about fertility.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of PEGINTRON. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PEGINTRON?

- Before mixing, store PEGINTRON single-dose REDIPEN in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Before mixing, store PEGINTRON vials at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep PEGINTRON away from heat.
- After mixing, use PEGINTRON right away or store it in the refrigerator for up to 24 hours between 36°F to 46°F (2°C to 8°C).
- Do not freeze PEGINTRON.
- **Keep PEGINTRON and all medicines out of the reach of children.**

General Information about the safe and effective use of PEGINTRON

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PEGINTRON for a condition for which it was not prescribed. Do not give PEGINTRON to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about PEGINTRON that was written for healthcare professionals.

What are the ingredients in PEGINTRON?

Active ingredients: peginterferon alfa-2b

Inactive ingredients: dibasic sodium phosphate anhydrous, monobasic sodium phosphate dihydrate, sucrose, polysorbate 80. Sterile water for injection is supplied as a diluent.

Manufactured by:

Merck Sharp & Dohme Corp., a subsidiary of **Merck & Co., Inc.**, Whitehouse Station, NJ 08889, USA

U.S. License Number 0002

For patent information: www.merck.com/product/patent/home.html

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For more information call 1-800-526-4099.

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