

MEDICATION GUIDE
SYLATRON™ (SY-LA-TRON)
(Peginterferon alfa-2b)

Read this Medication Guide before you start taking SYLATRON, and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment.

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

SYLATRON can cause serious mental health problems which can lead to suicide. Signs and symptoms can include:

- depression (feeling so sad or hopeless that it interferes with your life or you have thoughts of hurting yourself)
- aggressive behavior towards others, or thoughts of hurting others
- memory changes and confusion

Call your healthcare provider if you have any of these signs or symptoms or if they get worse.

See **“What are the possible side effects of SYLATRON?”** for more information about side effects.

What is SYLATRON?

SYLATRON is a prescription medicine that is used to prevent malignant melanoma (a kind of skin cancer) from coming back after it has been removed by surgery. SYLATRON should be started within 84 days of surgery to remove lymph nodes containing cancer.

It is not known if SYLATRON is safe and effective in children less than 18 years of age.

Who should not take SYLATRON?

Do not take SYLATRON:

- if you have had a serious allergic reaction to peginterferon alfa-2b or to interferon alfa-2b
- if you have certain types of hepatitis
- if you have severe liver damage

What should I tell my healthcare provider before taking SYLATRON?

Before you take SYLATRON, tell your healthcare provider about all of your health problems, including if you:

- are being treated for a mental illness or had treatment in the past for mental illness, including depression or thoughts of suicide or suicide attempts. See **“What is the most important information I should know about SYLATRON?”**
- have severe liver damage from drugs or disease
- have or had an overactive or underactive thyroid gland
- have diabetes
- have any other medical problem(s)
- are pregnant or plan to become pregnant. It is not known if SYLATRON will harm your unborn baby.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you should use SYLATRON or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

SYLATRON and certain other medicines may affect each other and cause side effects.

Know the medicines you take. Keep a list of them to show your doctors and pharmacists each time you get a new medicine.

You should not start a new medicine before your talk with the healthcare provider who prescribes you SYLATRON.

How should I take SYLATRON?

- Take SYLATRON exactly as your healthcare provider tells you to.
- SYLATRON is given as an injection under your skin (subcutaneous injection). Your healthcare provider should show you how to prepare and measure your dose of SYLATRON, and how to inject yourself before you use SYLATRON for the first time.
- Do not take more than your prescribed dose. Call your healthcare provider right away if you take too much SYLATRON.
- Inject SYLATRON one time each week unless instructed differently by your healthcare provider. Call your healthcare provider for instructions if you miss a dose.
- Expect to get “flu-like” symptoms when taking SYLATRON. To help reduce flu-like symptoms:
 - You should take 500 mg to 1,000 mg of acetaminophen 30 minutes before your first dose of SYLATRON.
 - Follow your healthcare provider’s instructions about taking acetaminophen before future doses of SYLATRON.
 - Inject SYLATRON at bedtime to help reduce flu-like symptoms.

Your healthcare provider should do blood tests before starting and during treatment with SYLATRON.

It is important for you to keep all appointments with your healthcare provider. Call your healthcare provider if you miss an appointment. There may be special instructions for you.

What are the possible side effects of SYLATRON?

SYLATRON can cause serious side effects or worsen existing problems, including:

See **“What is the most important information I should know about SYLATRON?”**.

- **Heart problems.** Signs and symptoms can include:
 - fast heart rate or abnormal heart beat
 - trouble breathing or chest pain
- **Serious eye problems.** Symptoms can include:
 - decrease in vision
 - blurred vision
- **Severe or worsening liver problems.** Symptoms can include:
 - yellowing of your skin or the white part of your eyes
 - swelling of your stomach area (abdomen)
- **Thyroid problems.** Signs and symptoms can include:
 - problems concentrating
 - feeling cold or hot all of the time
 - weight changes
- **High blood sugar (diabetes).** Signs and symptoms can include:
 - increased thirst
 - urinating more often than normal
 - weight loss
 - your breath smells like fruit

Call your healthcare provider right away if you have any of these serious side effects.

The most common side effects of SYLATRON include:

- flu-like symptoms, which may include fever, headache, tiredness, muscle or joint aches, chills, nausea, or loss of appetite
- feeling sad or depressed
- redness, swelling, or itching around the injection site
- changes in blood tests measuring how your liver works

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

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

You may also report side effects to Schering Corporation at 1-800-526-4099.

How should I store SYLATRON?

- Store SYLATRON vials in the carton at 59°F to 86°F (15°C to 30°C).
- After mixing, use SYLATRON right away or store it in the refrigerator for no longer than 24 hours at 36°F to 46°F (2°C to 8°C).
- Do not freeze SYLATRON.

Keep SYLATRON and all medicines out of the reach of children.

General information about the safe and effective use of SYLATRON

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SYLATRON for a condition for which it was not prescribed. Do not give to other people; it may harm them.

This Medication Guide summarizes the most important information about SYLATRON. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider for information about SYLATRON that is written for healthcare professionals.

For more information, go to www.SYLATRON.com or call 1-800-526-4099.

What are the ingredients in SYLATRON?

Active ingredient: peginterferon alfa-2b

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

The Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by Schering Corporation
Kenilworth, NJ 07033 USA

Issued: March 2011

31858704T