MEDICATION GUIDE

SYLATRON™ (SY-LA-TRON)

(Peginterferon alfa-2b)

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

SYLATRON can cause serious mental health problems which can lead to suicide.

SYLATRON may cause you to develop mood or behavior problems that may get worse during treatment with SYLATRON or after your last dose. Call your healthcare provider right away if you, your family, or caregiver notice any of the following:

- irritability (getting upset easily)
- depression (feeling low, feeling bad about yourself, or feeling hopeless)
- aggressive behavior, 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 SYLATRON and for 6 months after your last dose.

If symptoms get worse or become severe and continue, your healthcare provider may tell you to stop taking SYLATRON permanently. These signs or symptoms may not go away after you stop taking SYLATRON.

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
- have certain types of hepatitis
- 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 hurting yourself or others or suicide attempts. See "**What is the most important information I should know about SYLATRON?**"
- have liver damage from drugs or cirrhosis or other liver disease
- have kidney problems or are receiving kidney dialysis treatment
- have ever been addicted to drugs or alcohol
- have or had an overactive or underactive thyroid gland
- have diabetes
- have any other medical problems
- are pregnant or plan to become pregnant. SYLATRON can harm your unborn baby.
    - Females who are able to become pregnant should use effective birth control (contraception) during treatment with SYLATRON and for at least 10 days after the final dose of SYLATRON.
    - Your healthcare provider should do a pregnancy test before you begin taking SYLATRON. Tell your healthcare provider right away if you become pregnant or you think you might be pregnant during treatment with SYLATRON.
- are breastfeeding or plan to breastfeed. It is not known if SYLATRON passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take SYLATRON.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter 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 healthcare provider and pharmacist 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. Your healthcare provider will tell you how much SYLATRON to take and when to take it.
- 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.
- 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.
- 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.
  - Drink plenty of fluids.
- Your healthcare provider should do blood tests before you start and regularly during treatment with SYLATRON.
- Your healthcare provider will monitor you for side effects during treatment with SYLATRON. If needed, your healthcare provider may:
  - keep your prescribed dose the same
  - reduce your prescribed dose
  - tell you to skip a dose or doses, or
  - tell you to stop taking SYLATRON permanently

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 Merck Sharp & Dohme Corp., a subsidiary of **Merck & Co., Inc.**, at 1-877-888-4231.

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 SYLATRON to other people, even if they have the same symptoms that you have. 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.

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.

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, go to www.SYLATRON.com or call 1-877-888-4231.

This Medication Guide has been approved by the U.S. Food and Drug Administration Revised: 12/2018