

Medication Guide
PLEGRIDY™ (PLEGG-rih-dee)
(peginterferon beta-1a) injection for subcutaneous use

Read this Medication Guide before you start using PLEGRIDY, and each time you get a refill. There may be new information. This information 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 PLEGRIDY?

PLEGRIDY can cause serious side effects, including:

- Liver problems or worsening of liver problems, including liver failure and death. Symptoms may include: yellowing of your skin or the white part of your eye, nausea, loss of appetite, tiredness, bleeding more easily than normal, confusion, sleepiness, dark colored urine, and pale stools.
- During your treatment with PLEGRIDY you will need to see your healthcare provider and have regular blood tests to check for these possible side effects.
- Depression or suicidal thoughts. Symptoms may include: new or worsening depression (feeling hopeless or bad about yourself), thoughts of hurting yourself or suicide, irritability (getting upset easily), nervousness, or new or worsening anxiety.

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

What is PLEGRIDY?

- PLEGRIDY is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- It is not known if PLEGRIDY is safe and effective in people under 18 or over 65 years of age.

Who should not use PLEGRIDY?

Do not take PLEGRIDY if you:

- are allergic to interferon beta or peginterferon beta-1a, or any of the other ingredients in PLEGRIDY. See the end of this Medication Guide for a complete list of ingredients in PLEGRIDY.

Before using PLEGRIDY, 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 suicidal behavior
- have or had liver problems, low blood cell counts, bleeding problems, heart problems, seizures (epilepsy), thyroid problems, or any kind of autoimmune disease
- take prescription and over-the-counter medicines, vitamins, and herbal supplements
- are pregnant or plan to become pregnant. It is not known if PLEGRIDY will harm your unborn baby. Tell your healthcare provider if you become pregnant during your treatment with PLEGRIDY.
 - If you become pregnant while taking PLEGRIDY, talk to your doctor about enrolling in the PLEGRIDY Pregnancy Registry. You can enroll in this registry by calling 1-866-810-1462 or visiting <https://www.plegridypregnancyregistry.com/>. The purpose of this registry is to collect information about the safety of Plegridy during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if PLEGRIDY passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you use PLEGRIDY.

How should I use PLEGRIDY?

- See the **Instructions for Use** for detailed instructions to prepare for and to inject your dose of PLEGRIDY.
- Use PLEGRIDY exactly as your healthcare provider tells you. A healthcare provider should show you how to inject your PLEGRIDY before you use it for the first time.
- When you first use PLEGRIDY, your healthcare provider may tell you to slowly increase your dose so that you can adjust to the effects of PLEGRIDY before using the full dose. You should use a PLEGRIDY starter pack to slowly adjust your dose when you begin treatment.
- PLEGRIDY is given by injection under the skin (subcutaneous injection) of your stomach (abdomen), back of

upper arm, or thigh 1 time every 14 days.

- Change (rotate) the site you choose with each injection to help decrease the chance that you will have an injection site reaction. **Do not** inject into an area of the body where the skin is irritated, reddened, bruised, infected, or scarred in any way.
- Always use a new, PLEGRIDY prefilled pen or new, unopened single-use prefilled syringe for each injection.

What are the possible side effects of PLEGRIDY?

See “What is the most important information I should know about PLEGRIDY?”

PLEGRIDY may cause additional serious side effects, including:

- **serious allergic reactions.** Serious allergic reactions can happen quickly. Symptoms may include: itching, swelling of the face, eyes, lips, tongue, or throat, trouble breathing, feeling faint, anxiousness, skin rash, hives, skin bumps.
- **injection site reactions.** PLEGRIDY may commonly cause redness, pain, or swelling at the place where your injection was given. Call your healthcare provider right away if an injection site becomes swollen and painful or the area looks infected and it does not heal within a few days. You may have a skin infection or an area of severe skin damage (necrosis) requiring treatment by a healthcare provider.
- **heart problems, including congestive heart failure.** While PLEGRIDY is not known to have any direct effects on the heart, some people who did not have a history of heart problems developed heart muscle problems or congestive heart failure after taking interferon beta. If you already have heart failure, PLEGRIDY may cause your heart failure to get worse. Call your healthcare provider right away if you have worsening symptoms of heart failure such as shortness of breath or swelling of your lower legs or feet while using PLEGRIDY.
 - Some people using PLEGRIDY may have other heart problems, including low blood pressure, fast or abnormal heart beat, chest pain, heart attack, or a heart muscle problem (cardiomyopathy).
- **autoimmune diseases.** Problems with easy bleeding or bruising (idiopathic thrombocytopenia), thyroid gland problems (hyperthyroidism and hypothyroidism), and autoimmune hepatitis have happened in some people who use interferon beta.
- **blood problems and changes in your blood tests.** PLEGRIDY can decrease your white blood cells or platelets, which can cause an increased risk of infection, bleeding, or anemia and can cause changes in your liver function tests. Your healthcare provider should do blood tests while you use PLEGRIDY to check for side effects.
- **seizures.** Some people have had seizures while taking PLEGRIDY, including people who have never had seizures before.

The most common side effects of PLEGRIDY include:

- **flu-like symptoms.** Many people who use PLEGRIDY have flu-like symptoms early in the course of therapy. These symptoms are not really the flu. You cannot pass it on to anyone else. **Symptoms may include:** headache, muscle and joint aches, fever, chills, or tiredness.
 - You may be able to manage these flu-like symptoms by taking over-the-counter pain and fever reducers and drinking plenty of water. For many people, these symptoms lessen or go away over time.

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

General Information about the safe and effective use of PLEGRIDY.

Medicines are sometimes prescribed for purposes other than those listed in this Medication Guide. If you would like more information, talk to your healthcare provider or pharmacist. You can ask your healthcare provider or pharmacist for information about PLEGRIDY that is written for health professionals. Do not use PLEGRIDY for a condition for which it was not prescribed. Do not give PLEGRIDY to other people, even if they have the same symptoms that you have. It may harm them. For more information, go to www.plegridy.com or call 1-800-456-2255

What are the ingredients in PLEGRIDY?

Active ingredient: peginterferon beta-1a

Inactive ingredients:

- **Single-Use Prefilled Pen:** sodium acetate trihydrate, glacial acetic acid, arginine hydrochloride,

polysorbate 20 in water for injection

- **Single-Use Prefilled Syringe:** sodium acetate trihydrate, glacial acetic acid, arginine hydrochloride, polysorbate 20 in water for injection

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

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