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Interferon Beta-1b Injection

pronounced as (in" ter feer' on bay' ta wun bee)

Why is this medication prescribed?

Interferon beta-1b injection is used to reduce episodes of symptoms in patients with relapsing-remitting (course of disease where symptoms flare up from time to time) of multiple sclerosis (MS, a disease in which the nerves do not function properly and patients may experience weakness, numbness, loss of muscle coordination and problems with vision, speech, and bladder control). Interferon beta-1b is in a class of medications called immunomodulators. It is not known exactly how interferon beta-1b works to treat MS.

How should this medicine be used?

Interferon beta-1b injection comes as a powder to be mixed with liquid and injected subcutaneously (just under the skin). It is usually injected every other day. Inject interferon beta-1b injection at around the same time of day each time you inject it. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Use interferon beta-1b injection exactly as directed. Do not inject more or less of it or inject it more often than prescribed by your doctor. Your doctor will probably start you on a low dose of interferon beta-1b injection and gradually increase your dose.

You will receive your first dose of interferon beta-1b in your doctor's office. After that, you can inject interferon beta-1b yourself or have a friend or relative perform the injections. Before you use interferon beta-1b yourself the first time, read the written instructions that come with it. Ask your doctor or pharmacist to show you or the person who will be injecting the medication how to inject it.

Never reuse or share syringes, needles, or vials of medication. Throw away used needles and syringes in a puncture-resistant container and throw away used vials of medication in the trash. Talk to your doctor or pharmacist about how to dispose of the puncture-resistant container.

You should only mix one vial of interferon beta-1b at a time. It is best to mix the medication right before you plan to inject it. However, you may mix the medication in advance, store it in the refrigerator, and use it within 3 hours.

You can inject interferon beta-1b anywhere on your abdomen, buttocks, the back of your upper arms, or your thighs, except the area near your navel (belly button) and waistline. If you are very thin, only inject

in your thigh or the outer surface of your arm. Refer to the diagram in the manufacturer's patient information for the exact places you can inject. Choose a different spot each time you inject your medication. Do not inject your medication into skin that is irritated, bruised, reddened, infected, or scarred.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with interferon beta-1b and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before receiving interferon beta-1b injection,

- tell your doctor and pharmacist if you are allergic to interferon beta-1b injection, other interferon beta medications (Avonex, Plegridy, Rebif), any other medications, human albumin, mannitol, or any of the other ingredients in interferon beta-1b injection. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you drink or have ever drunk large amounts of alcohol, if you have or have ever had anemia (low red blood cells) or low white blood cells, blood problems such as bruising easily or bleeding, seizures, mental illness such as depression, especially if you have ever thought about killing yourself or tried to do so, heart failure, or heart or liver disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while receiving interferon beta-1b injection, call your doctor.
- ask your doctor about the safe use of alcoholic beverages while receiving interferon beta-1b injection. Alcohol can make the side effects from interferon beta-1b worse.
- you should know that you may have flu-like symptoms such as headache, fever, chills, sweating, muscle aches, and tiredness after your injection. Your doctor may tell you to take an over-the-counter pain and fever medication to help with these symptoms. Talk to your doctor if these symptoms are difficult to manage or become severe.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you miss a dose of interferon beta-1b injection, inject your next dose as soon as you remember or are able to give it. Your next injection should then be given about 48 hours (2 days) after that dose. Do not use interferon beta-1b injection two days in a row. Do not inject a double dose to make up for a missed dose. Call your doctor if you miss a dose and have questions about what to do.

What side effects can this medication cause?

Interferon beta-1b injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- vaginal bleeding or spotting between menstrual periods
- tight muscles
- weakness
- changes in sex drive or ability (in men)
- change in coordination

Some side effects can be serious. If you experience any of these symptoms or any of the symptoms listed in the SPECIAL PRECAUTIONS section, call your doctor immediately or get emergency medical treatment:

- bruising, pain, redness, swelling, or tenderness at the injection site
- blackening of skin or drainage at the injection site
- yellowing of the skin or eyes
- dark urine
- extreme tiredness
- pale stool
- nausea
- vomiting
- loss of appetite
- unusual bruising or bleeding
- confusion
- irritability
- nervousness
- difficulty falling asleep or staying asleep
- thinking about harming or killing yourself or planning or trying to do so
- anxiety
- new or worsening depression
- aggressive or violent behavior
- seeing things or hearing voices that do not exist
- acting without thinking
- seizures

- shortness of breath
- fast or abnormal heartbeat
- chest pain or tightness
- pale skin
- increased urinary frequency, especially at night
- rash
- hives
- itching
- swelling of the eyes, face, mouth, tongue, throat, hands, arms, feet, ankles, or lower legs
- difficulty breathing or swallowing
- red or bloody stools or diarrhea
- stomach pain
- slow or difficult speech
- purple patches or pinpoint dots (rash) on the skin
- decreased urination or blood in the urine

Interferon beta-1b injection may cause other side effects. Call your doctor if you have any unusual problems while receiving this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store vials of interferon beta-1b powder at room temperature and away from excess heat and moisture (not in the bathroom). If necessary, vials containing prepared interferon beta-1b solution may be stored in the refrigerator for up to 3 hours after mixing. Do not freeze interferon beta-1b.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and

young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to interferon beta-1b injection.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Betaseron[®]
- Extavia[®]

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