Betaseron® (bay ta SEER on)

Generic name: interferon beta-1b (in ter FEER on, BAY ta, won bee)

What is Betaseron®?
Interferons are proteins made in the body to regulate the immune system. They provide chemical signals that increase or decrease the activity of various cell types within the immune system. Betaseron® was made by splicing the human gene for interferon beta-1b into e. coli bacteria. The interferon made by these bacteria is isolated and purified to make the medication.

Betaseron® decreases the ability of immune cells to react to myelin antigens. It shifts the immune reaction away from T_H1 type cells (which tend to promote autoimmune reactions) and towards T_H2 type cells (which tend to block autoimmune disease). It also makes it more difficult for cells to cross from the bloodstream into the brain. This medicine does not suppress the immune system, and patients taking it do not have an increased risk of infection.

Betaseron® slows the course of multiple sclerosis when used regularly over long periods of time. It does not improve existing symptoms and is not used to treat acute MS attacks.

Starting on Betaseron®.
To obtain Betaseron®, a form must be completed and faxed to the BETAPLUS™ program. This program, operated by Bayer Healthcare Pharmaceuticals (the manufacturer of Betaseron®), will start the process of obtaining the medication. The MS Center staff will assist with completion of these forms and getting insurance approval. It takes about 10-14 days to get insurance approval. The medication is then shipped overnight to either your home or your pharmacy (depending on insurance requirements).

After the medication arrives, those living near the Center should contact our nurse for training on how to administer the Betaseron®. Those living outside our region will have training done by visiting nurses.

When first starting Betaseron®, it should be started at a low dose and tapered upwards. This is done by mixing and drawing up the medication into the syringe, and then squirting part of it out into the sink. A typical way of tapering upwards is:

- Weeks 1-2 Use ¼ of the dose
- Weeks 3-4 Use ½ of the dose
- Weeks 5-6 Use ¾ of the dose
- Week 7 and on use full dose
Betaseron® often causes aching andfevers (flu-like side effects) when first starting on the medication. These occur about an hour after the injection, and last about 8 hours. These side effects can be minimized by:

- Taper upwards from a low dose when starting the medication (see above)
- Take medications for this in the beginning. These should be taken at the time of the injection and if needed the following day. They should be taken with each dose until the full dose of Betaseron® is achieved. At that time, if side effects are tolerable then the medications to prevent these side effects can be tapered. Medications that help minimize the flu-like side effects include:
  - Ibuprofen (Advil, Motrin): can take up to 800mg three times a day
  - Naproxen (Aleve): can take up to 250-550mg twice a day
  - Aspirin: can take up to 650mg every six hours
  - Acetaminophen (Tylenol and others): can take up to 650-1000mg every 6 hours
- Inject the medication at bedtime so that most of the side effects occur during sleep

**How should Betaseron® be taken?**
Betaseron® is given by injection under the skin.
- Volume injected: 1mL (1 cc).
- Needle size: 30 gauge, ½ inch length
- Autoinjector: available for those who want to use it.
- Frequency: every other day
- Injection site locations: Injections should be rotated among various sites. Sites include front of the thighs, back of arms, buttocks and abdomen.
- Mixing: Betaseron® comes in a dry powder that is mixed with saline prior to injection. The medication should be used within three hours of mixing.

Laboratory tests should be done to check for blood counts and liver function. There is no standard frequency for these tests, but our Center does blood tests about every three months during the first year with lesser frequencies after that. Thyroid testing is indicated if symptoms of thyroid dysfunction develop.

**What if a dose is missed?**
Take the next dose as soon as you can after remembering. Doses should be given about 48 hours apart.

**How should Betaseron® be stored?** Room temperature

**How supplied:** Betaseron® comes in prepackaged kits containing all needed supplies. It comes in single dose vials with 0.3mg of lyophilized powder each. There are 14 vials per pack.

**What are the common side effects?**
• Injection site reactions: It is common to get a red spot at the site of the injection. This is sometimes accompanied by a lump under the skin or itching. On rare occasion, the injection site may break down into a sore (necrosis) that may be slow to heal. Injection site reactions can be minimized by:
  o Keep the needle and other equipment clean.
  o Rotating the sites. If particular body locations are more prone to these reactions, those sites may be removed from the rotation.
  o Some find that applying warm packs before or after the injection may help. Others find that cool packs help. Experiment to see which works best for you.
  o Set the needle depth deeper to keep the medication from reacting just beneath the skin.
  o Don’t remove the air bubble, and don’t squirt the drug out the end of the needle that you use to inject with. The medication left on the tip of the needle may track to the surface of the skin.
  o Lidocaine creams such as Emla® or Elamax® may decrease injection site pain on the surface of the skin
  o Hydrocortisone cream may decrease the inflammation.
• Injection site bruising: This is caused by blood leaking along the needles tract. This can be minimized by applying firm pressure to the injection site for a full minute, immediately after removing the needle.
• Flu-like side effects: Aching and fevers are common after these injections. Gastrointestinal symptoms (nausea, vomiting, diarrhea) are not usually seen with this medication. This side effect responds to tapering of the dose, use of analgesics, and taking the medication at bedtime (see above).
• Liver injury. Rarely, liver injury may occur. This is monitored with periodic blood tests. Action is usually not needed unless laboratory tests are elevated more than three times above normal. The changes are reversible if the medication is stopped or the dose reduced.
• White blood counts commonly decrease. There is no need to adjust the medication unless the white blood count falls excessively.
• Depression. It is uncertain whether this medication causes depression. Depression should be monitored in those taking the medication.
• Thyroid dysfunction may occur. If symptoms develop then blood testing for thyroid function is recommended.

Sharps container: Needles must be disposed of properly. We recommend using a needle clipper such as the Becton Dickinson Safe-Clip™ (www.bd.com/us/diabetes). This clips off the needles, allowing the rest of the syringe to be disposed of in the trash. Other disposal options may be available through your local solid waste disposal company.

Company Support:
BETAPLUS™ 1-800-788-1467 Provides financial assistance, insurance assistance, information about Betaseron® and multiple sclerosis.
www.betaseron.com
Insurance billing code: J1830