

Medication Guide
Betaseron® (bay-ta-seer-on)
Interferon beta-1b
(in-ter-feer-on beta-one-be)

Please read this leaflet carefully before you start to use Betaseron® and each time your prescription is refilled since there may be new information. The information in this medication guide does not take the place of talking with your doctor or healthcare professional.

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

Betaseron will not cure multiple sclerosis (MS) but it has been shown to decrease the number of flare-ups of the disease. Betaseron can cause serious side effects, so before you start taking Betaseron, you should talk to your doctor about the possible benefits of Betaseron and its possible side effects to decide if Betaseron is right for you. Potential serious side effects include:

- **Depression.** Some patients treated with interferons, including Betaseron, have become seriously depressed (feeling sad). Some patients have had thoughts about or have attempted to kill themselves. Depression (a sinking of spirits or sadness) is not uncommon in people with multiple sclerosis. However, if you are feeling noticeably sadder or helpless, or feel like hurting yourself or others, you should tell a family member or friend right away and call your doctor or health care provider as soon as possible. Your doctor may ask that you stop using Betaseron. Before starting Betaseron, you should also tell your doctor if you have ever had any mental illness, including depression, and if you take any medications for depression.
- **Risk to pregnancy.** If you become pregnant while taking Betaseron you should stop using Betaseron immediately and call your doctor. Betaseron may cause you to lose your baby (miscarry) or may cause harm to your unborn child. You and your doctor will need to decide whether the potential benefit of taking Betaseron is greater than the potential risks to your unborn child.
- **Allergic reactions.** Some patients taking Betaseron have had severe allergic reactions leading to difficulty breathing and swallowing. Allergic reactions can happen after your first dose or may not happen until after you have taken Betaseron many times. Less severe allergic reactions such as rash, itching, skin bumps or swelling of the mouth and tongue can also happen. If you think you are having an allergic reaction, stop using Betaseron immediately and call your doctor.
- **Injection site problems.** Betaseron may cause redness, pain or swelling at the place where an injection was given. A few patients have developed skin infections or areas of severe skin damage (necrosis). If one of your injection sites becomes swollen and painful or the area looks infected and it doesn't heal within a few days, you should call your doctor.

What is Betaseron?

Betaseron is a type of protein called beta interferon that occurs naturally in the body. It is used to treat relapsing forms of multiple sclerosis. It will not cure your MS but may decrease the number of flare-ups of the disease. MS is a life-long disease that affects your nervous system by destroying the protective covering (myelin) that surrounds your nerve fibers. The way Betaseron works in MS is not known.

Who should not take Betaseron?

Do not take Betaseron if you:

- Have had allergic reactions such as difficulty breathing, flushing or hives to another interferon beta or to human albumin.

If you have any of the following conditions or serious medical problems, you should tell your doctor *before* taking Betaseron:

- Depression (a sinking feeling or sadness), anxiety (feeling uneasy, nervous, or fearful for no reason), or trouble sleeping
- Liver diseases
- Problems with your thyroid gland
- Blood problems such as bleeding or bruising easily and anemia (low red blood cells) or low white blood cells
- Epilepsy
- Are pregnant, breastfeeding, or planning to become pregnant

You should tell your doctor if you are taking any other prescription or non-prescription medicines. This includes any vitamin or mineral supplements, or herbal products.

How should I take Betaseron?

Betaseron is given by injection under the skin (subcutaneous injection) every other day. Your injections should be approximately 48 hours (two days) apart, so it is best to take them at the same time each day, preferably in the evening just before bedtime.

You may be started on a lower dose when you first start taking Betaseron. Your doctor will tell you what dose of Betaseron to use, and that dose may change based on how your body responds. You should not change your dose without talking with your doctor.

If you miss a dose, you should take your next dose as soon as you remember or are able to take it. Your next injection should be taken about 48 hours (two days) after that dose. **Do not take Betaseron® on two consecutive days.** If you accidentally take more than your prescribed dose, or take it on two consecutive days, call your doctor right away.

You should always follow your doctor's instructions and advice about how to take this medication. If your doctor feels that you, or a family member or friend may give you the injections, then you and/or the other person should be trained by your doctor or healthcare provider in how to give an injection. Do not try to

give yourself (or have another person give you) injections at home until you (or both of you) understand and are comfortable with how to prepare your dose and give the injection.

Always use a new, unopened, vial of Betaseron and syringe for each injection. Never reuse vials or syringes.

It is important that you change your injection site each time Betaseron is injected. This will lessen the chance of your having a serious skin reaction at the spot where you inject Betaseron. You should always avoid injecting Betaseron into an area of skin that is sore, reddened, infected or otherwise damaged.

At the end of this leaflet there are detailed instructions on how to prepare and give an injection of Betaseron. You should become familiar with these instructions and follow your doctor's orders before injecting Betaseron.

What should I avoid while taking Betaseron?

- **Pregnancy.** You should avoid becoming pregnant while taking Betaseron until you have talked with your doctor. Betaseron can cause you to lose your baby (miscarry).
- **Breast feeding.** You should talk to your doctor if you are breast feeding an infant. It is not known if the interferon in Betaseron can be passed to an infant in mother's milk, and it is not known whether the drug could harm the infant if it is passed to an infant.

What are the possible side effects of Betaseron?

- **Flu-like symptoms.** Most patients have flu-like symptoms (fever, chills, sweating, muscle aches and tiredness). For many patients, these symptoms will lessen or go away over time. You should talk to your doctor about whether you should take an over the counter medication for pain or fever reduction before or after taking your dose of Betaseron.
- **Skin reactions.** Soreness, redness, pain bruising or swelling may occur at the place of injection. (see: "*What is the most important information I should know about Betaseron?*").
- **Depression and anxiety.** Some patients taking interferons have become very depressed and/or anxious. There have been patients taking interferons who have had thoughts about killing themselves. If you feel sad or hopeless you should tell a friend or family member right away and call your doctor immediately. (see: "*what is the most important information I should know about Betaseron?*").
- **Liver problems.** Your liver function may be affected. Symptoms of changes in your liver include yellowing of the skin and whites of the eyes and easy bruising.
- **Blood problems.** You may have a drop in the levels of infection-fighting white blood cells, red blood cells, or cells that help you form blood clots. If drops in levels are severe, they can lessen your ability to fight infections, make you feel tired or sluggish or cause you to bruise or bleed easily.

- **Thyroid problems.** Your thyroid function may change. Symptoms of changes in the function of your thyroid include feeling cold or hot much of the time, change in your weight (gain or loss) without a change in your diet or amount of exercise you are getting.
- **Allergic reaction.** Some patients have had hives, rash, skin bumps or itching while they were taking Betaseron. There is also a rare possibility that you can have a life threatening allergic reaction. (see “What is the most important information I should know about Betaseron”)

Whether you experience any of these side effects or not, you and your doctor should periodically talk about your general health. Your doctor may want to monitor you more closely and ask you to have blood tests done more frequently.

General Information About Prescriptions Medicines

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This medication has been prescribed for your particular medical condition. Do not use it for another condition or give this drug to anyone else. If you have any questions you should speak with your doctor or health care professional. You may also ask your doctor or pharmacist for a copy of the information provided to them with the product. Keep this and all drugs out of the reach of children.

Instructions for Preparing and Giving Yourself an Injection of Betaseron

Collect all your supplies before you begin. You will need:

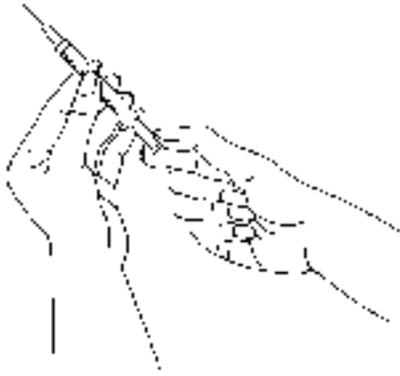
- a vial of Diluent for Betaseron (Sodium Chloride 0.54%)
- a vial of Betaseron
- 3-milliliter (3-mL) syringe with 21-gauge needle
- 1-milliliter (1-mL) syringe with 27-gauge needle
- alcohol wipes
- a puncture-resistant sealable container to dispose of used syringes/needles)
- antibacterial soap

Preparing for an injection:

- Check the expiration date. **Do not use if the medication is expired.** The expiration date is printed on the side of the carton and on the vial label.
- Wash your hands thoroughly with antibacterial soap and water.

Remove the protective caps from both vials. Clean the tops of the vials using the alcohol wipes. You should use one wipe per vial and leave the wipes on the tops of the vials until you are ready to use them.

- Remove the cover from the needle of the 3-mL syringe by pulling it straight off the needle.
- Pull the plunger of the 3-mL syringe back to the 1.2 mL mark.



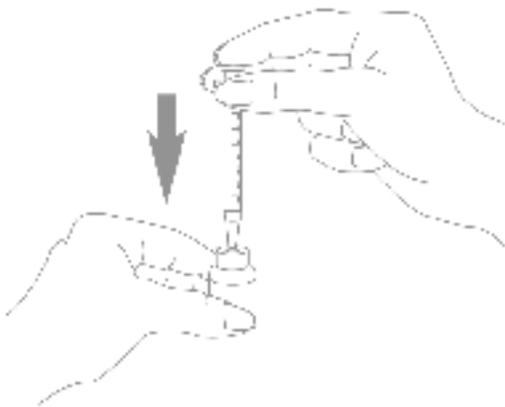
- Remove the wipe from the top of the vial of Diluent and place the vial on a stable surface. Slowly insert the needle on the 3 mL syringe straight through the stopper on top of the vial. Do not put the needle through the stopper more than once.

Be careful not to touch the needles or the rubber stoppers on the vials with your hands.

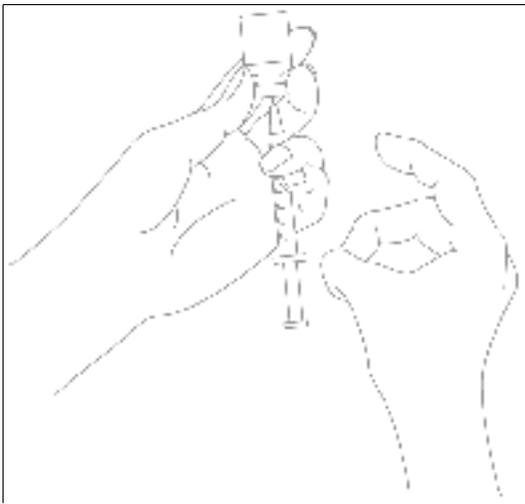
If you do touch a stopper, clean it with a fresh alcohol wipe.

If the needle touches anything other than the stopper throw away the entire syringe and needle into the disposal unit and start over with a new syringe.

- Push the plunger all the way down to gently inject the air in the syringe into the vial.



- Leaving the needle in the vial of Diluent for Betaseron, turn the vial upside down and make sure the liquid covers the needle tip.
- Resting your elbows on a stable surface, hold the vial and syringe in one hand and slowly pull back the plunger on the syringe to the 1.2 mL mark (to draw up that amount of liquid) with your other hand.
- Keeping the vial upside down, check for air bubbles in the syringe. If there are bubbles, gently tap the syringe with your fingers until any air bubbles that formed rise to the top of the barrel of the syringe.



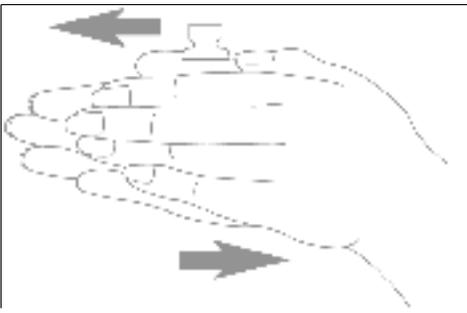
- Carefully push in the plunger to force air bubbles through the needle.
- Remove the needle/syringe from the vial of Diluent for Betaseron, but do not lay it down.
- Remove the alcohol wipe from the top of the vial of Betaseron, and slowly insert the needle of the syringe (containing 1.2 mL of liquid) all the way through the middle of the stopper on top of the vial.

Aiming the needle toward the side of the vial, slowly push the plunger down so the Diluent runs down the inside wall. Do not let the stream of Diluent fall directly onto the cake of Betaseron. Too direct or forceful a stream onto the drug cake can cause foaming.



Remove the needle/syringe from the vial and discard it into your disposal container.

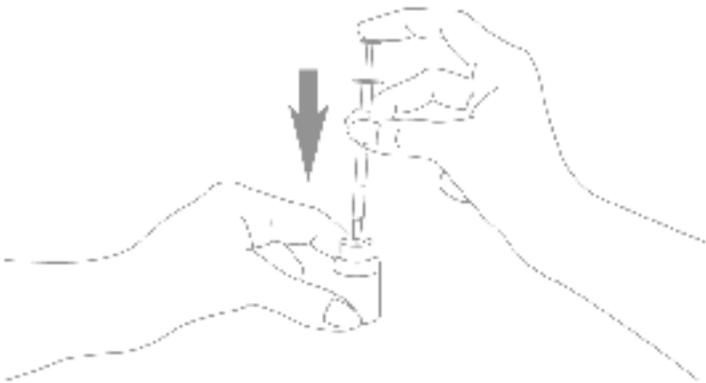
Gently roll the vial between your hands to completely dissolve the white cake of Betaseron (DO NOT SHAKE). Shaking can cause the Betaseron to foam. If there is foam, allow the vial to sit undisturbed until the foam settles.



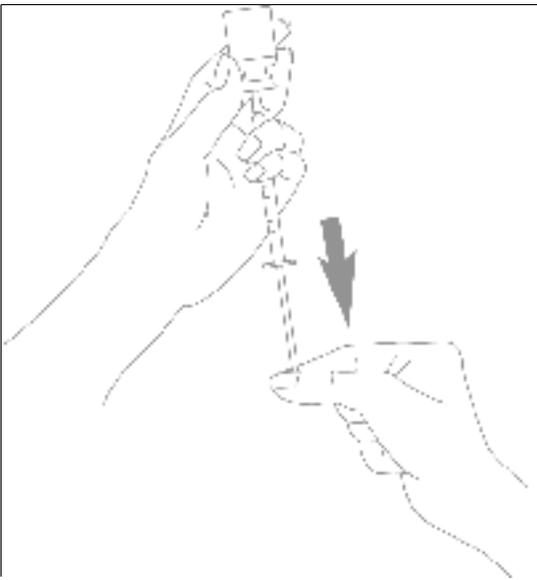
After the cake is dissolved, look closely at the solution. The solution should be clear and colorless. If the mixture contains particles or is discolored, do not use. Repeat the steps to prepare your dose using new vial(s). Contact Berlex at 1-888-237-5394 to obtain replacement vial(s)

Giving yourself an INJECTION

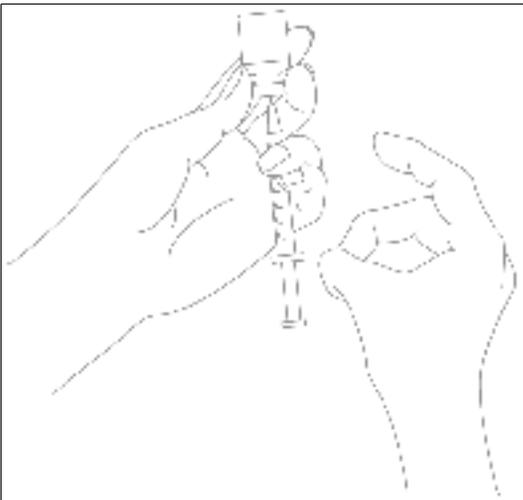
1. Use an alcohol wipe to re-clean the top of the Betaseron solution vial.
2. Remove the needle cap of the 1 mL syringe and pull back the plunger to the mark that matches the dose prescribed by your doctor.
3. Holding the vial of Betaseron solution on a stable surface, insert the needle of the 1 mL syringe through the middle of the stopper on the Betaseron solution vial.
4. Gently push the plunger all the way down to inject air into the vial.



5. Leaving the needle in the vial, turn the vial of Betaseron solution upside down and make sure the liquid covers the tip of the needle.
6. Pull the plunger back to the mark that matches your dose.



7. Keeping the vial with the syringe and needle pointing upward, check for air bubbles. If there are air bubbles, gently tap the syringe until any air bubbles that formed rise to the top of the barrel of the syringe.
8. Slowly push the plunger up to force the bubbles out through the needle. Make sure that the plunger is still at the mark that matches your dose.



9. Gently remove the needle and attached syringe from the vial.
10. Recap the needle on the syringe.
11. Throw away any unused solution remaining in the vial.

Note: The injection should be administered immediately after mixing (if the injection is delayed, refrigerate the solution and inject it within three hours). Do not freeze.

12. Choose a site to give yourself an injection (see diagram for areas); use a different area each day.

Picking an Injection Site

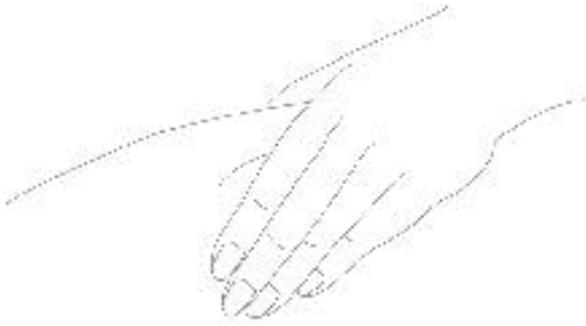
Betaseron (Interferon beta-1b) is injected under the skin and into the fat layer between the skin and the muscles (subcutaneous tissue). The best areas for injection are where the skin is loose and soft and away from the joints, nerves, and bones. Do not use the area near your navel or waistline. If you are very thin, use only the thigh or outer surface of the arm for injection.

You should pick a different site each time you give yourself an injection. The diagrams show different areas for giving injections. You should not choose the same area for two injections in a row. Keeping a record of your injections will help make sure you rotate your injection sites. You should decide where your injection will be given before you prepare your syringe for injection. If there are any sites that are difficult for you to reach, you can ask someone who has been trained to give injections to help you.

Remove the cap from the needle.

Hold the syringe like a pencil or dart in one hand.

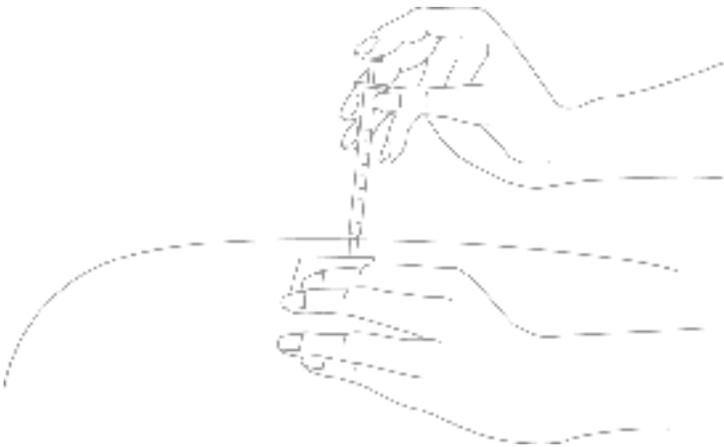
Gently pinch the skin around the site with the thumb and forefinger of the other hand.



While holding your skin, stick the needle straight into the skin at a 90° angle with a quick, firm motion. Once in your skin, slowly pull back on the plunger, if blood appears in the syringe it means that you have entered a blood vessel. Do not inject Betaseron. Withdraw the needle and repeat the steps to prepare your dose and choose and clean a new injection site. You should not use the same syringe; discard it in your puncture-proof container.

If no blood appears, slowly push the plunger all the way in until the syringe is empty.

Remove the needle from the skin then place a **dry cotton ball or gauze pad** over the injection site.



Gently massage the injection site for a few moments with the dry cotton ball or gauze pad.

Throw away the 1 mL syringe in the disposal container.

Disposing of syringes and needles

You should always check with your healthcare provider for instructions on how to properly dispose of used vials, needles and syringes. You should follow any special state or local laws regarding the proper disposal of needles and syringes.

DO NOT throw the needle or syringe in the household trash or recycle.

Always keep the disposal container out of the reach of children.

Storage Conditions

Betaseron is packaged as a powder in clear glass vials. Each package also contains a separate vial of liquid (diluent) to be used to dissolve the powder before injection.

Betaseron should be stored at room temperature (77°F), but may be stored between 58 and 86°F. Avoid freezing.

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

Manufactured by: Chiron Corporation, Emeryville, CA 94608

Distributed by: Berlex Laboratories, Montville, NJ 07045