

**Interferon beta-1b
(Betaseron®)**

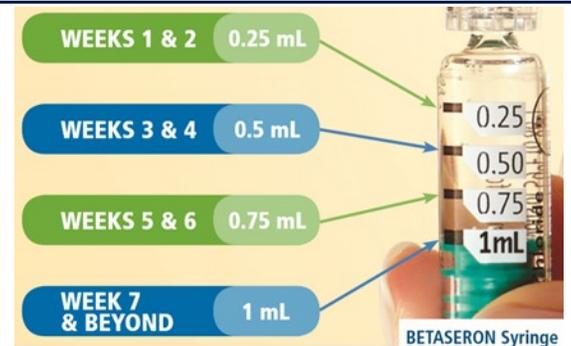
Patient Information

Updated: 10.2019

<p>USED FOR</p>	<ul style="list-style-type: none"> Relapsing-remitting forms of multiple sclerosis (MS) Interferon beta-1b (Betaseron) will not cure MS. It may prevent and reduce the number of flare-ups and slow disease progression.
<p>HOW IT WORKS</p>	<ul style="list-style-type: none"> Betaseron is made from human proteins called interferons thought to modify the immune processes responsible for injury to the nervous system from MS.
<p>HOW IT IS SUPPLIED</p>	<ul style="list-style-type: none"> Betaseron comes as a single use powder vial (0.3mg) with a single-dose prefilled syringe and an auto-injector syringe form. Betaseron powder vial and pre-filled syringe requires mixing of the powder vial with pre-filled syringe contents (containing Sodium Chloride, 0.54% solution). BETACONNECT™ Autoinjector (requires inserting an already mixed syringe into the device). <div data-bbox="1068 814 1479 1073" data-label="Image"> </div> <div data-bbox="1068 1087 1479 1325" data-label="Image"> </div>
<p>DOSE</p>	<ul style="list-style-type: none"> 0.25mg is injected under the skin (subcutaneously) every other day (every 48 hours). If you miss a dose do not inject 2 doses in a row. When first starting, a smaller dose is used, then gradually increased over 6 weeks according to a titration schedule (see next page). On the 7th week, use the full 0.25mg dose. Consider hydrating well and pre-medicating with Acetaminophen (Tylenol) or Ibuprofen (Advil) to prevent flu-like symptoms.

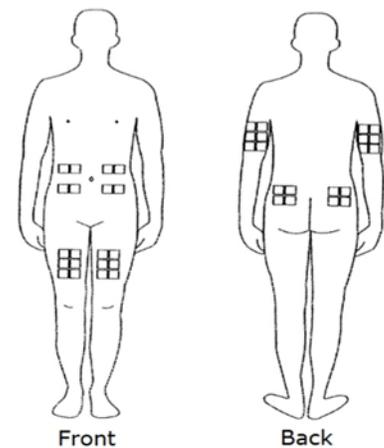
Titration Schedule

	Betaseron	% of full	Volume
Weeks 1-2	0.0625 mg	25%	0.25 mL
Weeks 3-4	0.125 mg	50%	0.5 mL
Weeks 5-6	0.1875 mg	75%	0.75 mL
Week 7 and thereafter	0.25 mg	100%	1 mL



HOW IT IS GIVEN

- Betaseron is injected into fatty area just under the skin in the areas shown to the right.
- Do not inject into an area of the where the skin is irritated, reddened, bruised, infected or scarred in any way.
- Rotate injection sites to avoid skin reactions.



STORAGE AND HANDLING

- When not used, store the powder vials at *room temperature* 20°C to 25°C (68°F to 77°F). Higher temperatures of 15°C to 30°C (59°F to 86°F) are permitted for up to *3 months*.
- After mixing of the powder, if not used immediately, refrigerate the syringe solution and use *within 3 hours*.
- Safely dispose of used syringes in a sharps container.



DRUG INTERACTIONS

- There are no known drug interactions with Interferon beta-1b (Betaseron).

COMMON SIDE EFFECTS

- **Flu- like symptoms:** muscle aches, fever, tiredness, chills.
- You may be able to manage with over-the counter (OTC) pain and fever reducers (Acetaminophen or Ibuprofen). For many people, these symptoms lessen or go away over time.
- Thyroid problems
- Change in liver function tests
- Injection site problems: redness, pain, swelling



RARE, BUT SERIOUS SIDE EFFECTS	<ul style="list-style-type: none"> • Tell your MS doctor right away if you have any of the following: <ul style="list-style-type: none"> • Depression and suicidal thoughts: feeling hopeless or feeling bad about yourself and having thoughts of hurting yourself. • Liver injury: symptoms may include nausea, loss of appetite, tiredness, dark colored urine and pale stools, yellowing of your skin or the white part of your eye (jaundice), bleeding more easily than normal, confusion, sleepiness. • Serious allergic and skin reactions: itching, swelling of your face, eyes, lips, tongue or throat, trouble breathing anxiousness, feeling faint, skin rash, hives, sores in your mouth or skin blisters and peels. • Skin necrosis at the injection site: any break in the skin, color changes (blue or black), swelling, drainage of fluid from the injection site. • Blood problems: low red and white blood cell, and platelet counts that can lead to infections and problems with bleeding and bruising.
MONITORING	<ul style="list-style-type: none"> • You should always check your skin for changes at the injection site. • During your treatment, you will need to have regular blood work to check for side effects. • BEFORE starting Betaseron, you will need a complete blood count and liver function tests. • AFTER starting Betaseron, you will need to repeat the blood work at 1 month, 3 months, and 6 months, then every 6 months thereafter.
MORE INFORMATION	<ul style="list-style-type: none"> • Websites: www.betaseron.com, www.nationalmssociety.org • Clinical Trials: <ul style="list-style-type: none"> • The IFNβ Multiple Sclerosis Study Group. Interferon beta-1b is effective in relapsing-remitting multiple sclerosis, I: clinical results of a multicenter, randomized, double-blind, placebo-controlled trial. <i>Neurology</i>. 1993;43:665-661.