Medication Guide
BETASERON
(bay-ta-seer-on)
interferon beta-1b
(in-ter-feer-on beta-one-be)

What is the most important information I should know about BETASERON?
BETASERON can cause serious side effects, including:

- **liver problems including liver failure.** Symptoms of liver problems may include:

• yellowing of your eyes	• itchy skin	• nausea or vomiting
• feeling very tired	• flu-like symptoms	• bruising easily or bleeding problems

  Your healthcare provider will do blood tests to check for these problems while you take BETASERON.
- **serious allergic reactions.** Serious allergic reactions can happen quickly and may happen after your first dose of BETASERON or after you have taken BETASERON many times. Symptoms may include difficulty breathing or swallowing, swelling of the mouth or tongue, rash, itching, or skin bumps.
- **depression or suicidal thoughts.** Call your healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:
  - thoughts about suicide or dying
  - new or worse anxiety
  - acting aggressive, being angry, or violent
  - hallucinations
  - new or worse depression
  - trouble sleeping (insomnia)
  - acting on dangerous impulses
  - other unusual changes in behavior or mood

What is BETASERON?
BETASERON is a prescription medicine used to treat relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. BETASERON is similar to certain interferon proteins that are produced in the body.
It is not known if BETASERON is safe and effective in children.

Who should not take BETASERON?
Do not take BETASERON if you are allergic to interferon beta-1b, to another interferon beta, to human albumin, or mannitol. See the end of this leaflet for a complete list of ingredients in BETASERON.

What should I tell my healthcare provider before taking BETASERON?
Before you take BETASERON, tell your healthcare provider if you:

- have or have had depression (sinking feeling or sadness), anxiety (feeling uneasy, nervous, or fearful for no reason) or trouble sleeping
- have or have had liver problems
- have or have had blood problems such as bleeding or bruising easily, low red blood cells (anemia) or low white blood cells
- have or have had seizures
- have or have had heart problems
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if BETASERON passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.
Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take BETASERON?

- See the Instructions for Use at the end of this Medication Guide for complete information on how to use BETASERON.
- BETASERON is given by injection under your skin (subcutaneous injection) every other day.
- Take BETASERON exactly as your healthcare provider tells you to take it.
- If your healthcare provider feels that you or someone else may give you the injections then you or the other person should be trained by your healthcare provider in how to give an injection.
- Do not try to give yourself or have another person give you injections until you or both of you understand and are comfortable with how to prepare your dose and give the injection.
- You may be started on a lower dose when you first start taking BETASERON. Your healthcare provider will tell you what dose of BETASERON to use.
- Your healthcare provider may change your dose of BETASERON. You should not change your dose without talking to your healthcare provider.
- 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 (2 days) after that dose. **Do not** take BETASERON on 2 consecutive days. If you accidentally take more than your prescribed dose, or take it on 2 consecutive days, call your healthcare provider right away.

- **Always use a new, unopened vial of BETASERON and pre-filled diluent syringe for each injection.** Throw away any unused medicine. **Do not** re-use any vials, syringes, or needles.
- It is important for you to change your injection site each time you inject BETASERON. This will lessen the chance of you having a serious skin reaction at the site where you inject BETASERON. Avoid injecting BETASERON into an area of skin that is sore, reddened, infected or has other problems.

What are the possible side effects of BETASERON?

BETASERON may cause serious side effects. Call your healthcare provider right away if you have any of the serious side effects of BETASERON including:

- **See "What is the most important information I should know about BETASERON?"**
- **heart problems**. BETASERON may worsen heart problems including congestive heart failure. Symptoms of heart problems may include:
  - swollen ankles
  - shortness of breath
  - not being able to lay flat in bed
  - tightness in chest
  - decreased ability to exercise
  - fast heartbeat
  - increased need to urinate at night
- **injection site problems**. Serious skin reactions can happen in some people including areas of severe damage to skin and the tissue below the skin (necrosis). These reactions can happen anywhere you inject BETASERON. Symptoms of injection site problems may include swelling, redness, or pain at the injection site, fluid drainage from the injection site, and breaks in your skin or blue-black skin discoloration.
- **flu-like symptoms.** BETASERON can cause flu-like symptoms including:
  - fever
  - tiredness
  - sweating
  - chills
  - muscle aches when you first start to use it

  These symptoms may decrease over time. Taking medicines for fever and pain relief on the days you are using BETASERON may help decrease these symptoms.
- **seizures**. Some people have had seizures while taking BETASERON, including people who have never had seizures before. It is not known if the seizures were related to their MS, to BETASERON, or to a combination of both. If you have a seizure after taking BETASERON call your healthcare provider right away.

The most common side effects of BETASERON include:

- low white blood cell count
- headache
- pain
- increases in your liver enzymes
- increases in your muscle tension
- rash
- problems sleeping
- weakness
- stomach pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of BETASERON. For more information, ask your healthcare provider or pharmacist.

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

How should I store BETASERON?

- Before mixing, store BETASERON at room temperature between 68°F to 77°F (20°C to 25°C).
- Before mixing, BETASERON may be stored for up to 3 months between 59°F to 86°F (15°C to 30°C).
- After mixing, you can refrigerate BETASERON for up to 3 hours before using. Your BETASERON must be used within 3 hours of mixing even if refrigerated.
- **Do not freeze.**

Keep BETASERON and all medicines out of the reach of children.

General information about the safe and effective use of BETASERON.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BETASERON for a condition for which it was not prescribed. Do not give BETASERON to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about BETASERON. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about BETASERON that is written for health professionals.

For more information, go to www.BETASERON.com or call BETAPLUS, the BETASERON patient support program, at 1-800-788-1467.

What are the ingredients in BETASERON?

Active ingredient: interferon beta-1b

Inactive ingredients: albumin (human), mannitol

Diluent contains sodium chloride solution.

This Medication Guide has been approved by the U.S. Food and Drug Administration 8/2019