

Home

Betaseron

Betaseron 🕁

Pronunciation: bay-ta-seer-on

Generic name: interferon beta-1b [in-ter-FEAR-on-BAY-ta-1b]

Dosage form: subcutaneous injection (0.3mg)

Drug class: Interferons

Medically reviewed by Melisa Puckey, BPharm. Last updated on Feb 9, 2024.

Uses Side effects Warnings Before taking Dosage Interactions

What is Betaseron?

Betaseron is used for relapsing forms of multiple sclerosis (MS), including relapsing-remitting multiple sclerosis (RRMS), isolated syndrome, and active secondary progressive disease in adults. Betaseron (interferon beta-1b) helps to reduce the number of flare-ups and clinical symptoms in relapsing forms of multiple sclerosis, but it will not cure MS. Betaseron injection works as it is similar to a protein in the body called interferon, which is involved in inflammation.

Betaseron is given as an injection under the skin every other day.

Betaseron injection received FDA approval on July 23, 1993, and can now be used to treat adults with relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. This includes people who have had their first symptoms of multiple sclerosis and have an MRI consistent with multiple sclerosis.

Betaseron side effects

Common Betaseron side effects may include:

- · low white blood cell counts;
- abnormal liver function tests;
- headache, weakness;
- sleep problems (insomnia);
- stomach pain;
- muscle pain, stiffness, or weakness;
- rash;
- flu symptoms; or
- a skin reaction where the medicine was injected.

Serious Betaseron side effects

Allergic reactions Get emergency medical help if you have signs of an allergic reaction to Betaseron injection: hives, difficulty breathing, swelling of your face, lips, tongue, or throat.

Liver problems including liver failure Symptoms of liver problems include yellowing of eyes, itchy skin, nausea or vomiting, feeling very tired, flu-like symptoms, and bruising easily or bleeding problems.

Depression Some patients using interferon medicines have become very depressed or had thoughts of suicide. Report any new or worsening symptoms of depression to your doctor, such as mood or behavior changes, anxiety, trouble sleeping, hallucinations, or if you feel impulsive, hostile, aggressive, depressed, or have thoughts about suicide or hurting yourself.

Other serious side effects Stop using Betaseron injection and call your doctor at once if you have:

- fever, chills, sweating, tiredness, body aches;
- a seizure:
- pain, swelling, redness, or skin changes where an injection was given;
- heart problems chest tightness, swelling, rapid weight gain, trouble lying flat in bed, feeling short of breath;
- liver problems nausea, vomiting, itching, easy bruising, unusual bleeding, dark urine, jaundice (yellowing of your skin or eyes); or
- new or worsening symptoms of lupus joint pain and a skin rash on your cheeks or arms that worsens in sunlight.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

<u>Betaseron side effects</u> (more detail)

Related/similar drugs

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Warnings

Betaseron may be harmful to an unborn baby or may cause a miscarriage. Do not use Betaseron if you are pregnant.

Tell your doctor if you are pregnant or plan to become pregnant during treatment.

Before using Betaseron, tell your doctor if you are allergic to any drugs, or if you have liver disease, a thyroid disorder, epilepsy or other seizure disorder, a bleeding or blood-clotting disorder, anemia (low red blood cells), or a history of depression or suicidal behavior.

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.

Some patients using interferon medications have become very depressed or had thoughts of suicide. Stop using Betaseron if you have symptoms of depression (sadness, crying, loss of interest in things you once liked) or if you have any thoughts of hurting yourself.

Interferon beta-1b can harm your liver. Call your doctor at once if you have nausea, vomiting, itching, bruising or bleeding, or yellowing of your skin or eyes.

To be sure Betaseron is not causing harmful effects, your blood and liver function will need to be tested on a regular basis. Your thyroid function may also need to be tested. Do not miss any scheduled appointments.

Before taking this medicine

You should not use Betaseron if you are allergic to interferon beta, albumin, or mannitol.

To make sure Betaseron is safe for you, tell your doctor if you have:

- · liver disease;
- · heart problems;
- · a seizure:
- depression, anxiety, or sleep problems;
- a bleeding or blood-clotting disorder;
- low white blood cell (WBC) counts;
- · anemia (lack of red blood cells); or
- · an allergy to latex.

Tell your doctor if you are pregnant or breastfeeding.

Betaseron pregnancy and breastfeeding warnings (more detail)

How should I use Betaseron?

Use Betaseron exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose.

Betaseron is injected under the skin, usually every other day. A healthcare provider may teach you how to properly use the medication by yourself.

Read and carefully follow any Instructions for Use provided with your medicine. Ask your doctor or pharmacist if you

don't understand all instructions.

Prepare an injection only when you are ready to give it. Do not use if the medicine looks cloudy, has changed colors, or has particles in it. Call your pharmacist for new medicine.

Your healthcare provider will show you where on your body to inject Betaseron. Use a different place each time you give an injection. Do not inject into the same place two times in a row.

You will need frequent medical tests.

Store unmixed Betaseron and the diluent at cool room temperature away from moisture and heat.

After mixing, store the medicine in the refrigerator and use within 3 hours. Do not freeze.

Each single-use vial (bottle) or prefilled syringe is for one use only. Throw it away after one use, even if there is still medicine left inside. Throw away any Betaseron that is not used within 3 months.

Use a needle and syringe only once and then place them in a puncture-proof "sharps" container. Follow state or local laws about how to dispose of this container. Keep it out of the reach of children and pets.

Betaseron Dosing information

Usual Betaseron Adult Dose for Multiple Sclerosis:

Initial dose: 0.0625 mg subcutaneously every other day, and increased (in 25% increments) every 2 weeks, over a 6

week period, to maintenance dose

Maintenance dose: 0.25 mg subcutaneously every other day

Schedule for dose titration:

Weeks 1 and 2: 0.0625 mg subcutaneously every other day (25% of recommended dose)

Weeks 3 and 4: 0.125 mg subcutaneously every other day (50% of recommended dose)

Weeks 5 and 6: 0.1875 mg subcutaneously every other day (75% of recommended dose)

Week 7 and beyond: 0.25 mg subcutaneously every other day (100% of recommended dose)

Betaseron Use: For the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

1 Detailed Betaseron dosage information

What happens if I miss a dose?

Use the missed dose as soon as you remember. Then wait at least 48 hours (2 days) before using another injection, and restart your dosing schedule at that time. Do not use more than one injection every 48 hours.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while using Betaseron?

Avoid injecting this medicine into skin that is sore, red, or infected.

Avoid drinking alcohol. It may increase your risk of liver problems.

What other drugs will affect Betaseron?

Other drugs may interact with interferon beta-1b, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all your current medicines and any medicine you start or stop using.

Betaseron drug interactions (more detail)

Does Betaseron interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.



Ingredients

Active ingredient: interferon beta-1b

Inactive ingredients: albumin (human), mannitol Diluent contains sodium chloride solution.

Company

Manufactured for: Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ 07981

Betaseron Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for Betaseron.

Betaseron (interferon beta-1b) - Bayer HealthCare Pharmaceuticals Inc.

Formulation type Strength
Single-Dose Vial 0.3 mg

References

1. Betaseron Full Prescribing Information FDA

More about Betaseron (interferon beta-1b)

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- Side effects
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- Multiple Sclerosis

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

প্ Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

10+ years FDA approved 1993

User Reviews & Ratings

7.1 / 10

9 Reviews

Images

Betaseron 0.3 mg lyophilized powder for subcutaneous injection

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