Betaseron®
Interferon beta-1b

DESCRIPTION
Betaseron® (interferon beta-1b) is a purified, synthetic, recombinant protein produced by recombinant DNA technology. Betaseron is the recombinant form of a naturally occurring human cytokine. The terms interferon (IFN) and interferon beta-1b (IFN-beta-1b) are used interchangeably to indicate the drug. Interferon is a naturally occurring hormone. In the body, IFN is a part of the immune system. Its production is triggered by the presence of viruses and other agents that may cause certain types of cancer or tissue damage. IFN can cause the production of proteins known as interferon-stimulated proteins. These proteins are thought to limit the growth of virus-infected cells. In addition, IFN may help the immune system identify and destroy virus-infected cells.

When injected into the body, interferons have a number of effects. Effective amounts of interferon can suppress the growth of cancer cells or reduce the severity or frequency of virus infections. Interferons are not cancer vaccines; they do not alter the course of cancer. Interferons are not effective against all types of cancer. The benefit-risk ratio may be different for different indications. Betaseron is a recombinant IFN-beta-1b that is identical in amino acid sequence with the natural hormone.

Betaseron is prescribed for the treatment of relapsing forms of multiple sclerosis (MS) in adults. It has been shown to reduce the number of clinical exacerbations and MRI changes in patients with relapsing forms of MS. Betaseron is also approved for the treatment of patients with active non-melanoma skin cancer due to a history of radiation therapy. Due to the potential for adverse reactions, including serious infections, Betaseron is available only with a prescription in the United States. The following sections of the brochure provide information about the use, dosage, administration, precautions, and side effects of Betaseron.

CLINICAL PHARMACOLOGY
General
Interferons are a family of naturally occurring proteins, produced by leukocytes in response to infection and other biological stimuli. These molecules are produced in the body in response to viral, bacterial, or fungal infection, and are essential for the maintenance of the immune system. Interferons act by inducing the production of proteins that inhibit viral replication or enhance the immune response to infection. Interferons are found in the human body in the skin and in the blood, and are produced by many different types of cells. Interferons are also found in the human body in the skin and in the blood, and are produced by many different types of cells. Interferons are important for the treatment of certain types of skin cancer, and are also used to treat certain types of viruses, such as the herpes virus. Interferons can also be used to treat certain types of infections, such as the common cold, and are important for the treatment of certain types of allergies. Interferons are also used to treat certain types of infections, such as the common cold, and are important for the treatment of certain types of allergies. Interferons are also used to treat certain types of infections, such as the common cold, and are important for the treatment of certain types of allergies.

Betaseron is a recombinant form of interferon beta-1b, a natural cytokine. Betaseron is approved by the U.S. Food and Drug Administration (FDA) for the treatment of relapsing forms of MS in adults. Betaseron is approved for use in patients with relapsing forms of MS who have had at least two exacerbations in the previous year and who have had a laboratory-supported diagnosis of MS.

Betaseron is supplied as a solution for injection in vials containing either 0.5 mg or 1 unit of interferon beta-1b per vial. The solution contains 15 mg Albumin (Human), USP, 15 mg Mannitol, USP, and 0.006 mg Sodium Metabisulfite, USP. Drug is supplied in single-use vials. Betaseron is for single use only. The vials are provided in boxes of 2, 6, or 12 vials. The solution is sterile and contains no preservative, detergent, or added antiseptics.

Betaseron is a glycoprotein, and has a molecular weight of approximately 18,000 daltons. The protein is composed of 165 amino acids and contains one disulfide bond. Betaseron is a single-chain glycoprotein that is composed of 165 amino acids and contains one disulfide bond. Betaseron is a single-chain glycoprotein that is composed of 165 amino acids and contains one disulfide bond.

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Instructions and follow your doctor's orders before injecting Betaseron. It is important that you change your injection site each time Betaseron is given. You should always follow your doctor's instructions and advice about how to store Betaseron. Other people may give you the injections, then you and/or the other person should be trained to give yourself the injections. If you need help training, consult the pharmacy where you purchased your Betaseron or your doctor. If you break open, or have lumps, bumps, or pain. Tell your doctor or healthcare provider.

Right Arm

Left Arm

Figure 2

Before the syringe is discarded, look closely at the solution to make sure it is clear and colorless and does not contain particles. If the syringe contains anything other than a clear and colorless solution or does not contain a white blood cells. You should tell your doctor if you are taking any other prescription or non-prescription medicines. This includes any vitamins or supplements, herbal products, or other medicines.

Liver diseases

Problems with your thyroid gland

Blood conditions such as bleeding or bruising easily and anemia

Depressions or feeling sad, anxiety (feel like crying), or need to be sad, or have no energy

Thyroid problems

Liver problems

Depression, feeling sad, anxiety (feel like crying), or need to be sad, or have no energy

What is Betaseron?

Betaseron is a type of protein called interferon that occurs naturally in the body. It is used to treat multiple sclerosis (MS) to slow or stop the damage that MS can cause and to keep the number of attacks (flares) of your MS under control. Do not use it if the medication has expired.

What should I tell my doctor before taking Betaseron?

Tell your doctor if you are pregnant, plan to become pregnant, breast-feeding, or nursing a baby. Tell your doctor if you have ever had any allergic reactions such as difficulty breathing, flushing or hives to Betaseron or any other medicines, or any blood or liver problems, or if you have any history of depression or anxiety.

How is Betaseron given?

Betaseron is given by injection under the skin (subcutaneous injection) every day. Your doctor will give you the vial and prefilled syringe. They will also give you a syringe containing diluent. You will need to give yourself the injection. The diluted medication is then injected directly into the skin using a syringe and a needle. The needles and syringes used to give Betaseron must be used only for Betaseron.

If you have any of the following conditions or serious medical problems, you should not take Betaseron:

• Pregnancy.

• Depressions or feeling sad, anxiety (feel like crying), or need to be sad, or have no energy

• Thyroid problems.

• Blood problems such as bleeding or bruising easily and anemia (low red blood cells)

• Liver diseases

• Kahihemoglobin.

• Pregnancy.

• Depressions or feeling sad, anxiety (feel like crying), or need to be sad, or have no energy

• Thyroid problems.

• Blood problems such as bleeding or bruising easily and anemia (low red blood cells)

• Liver diseases

• Kahihemoglobin.

Figure 1

Instructions for Preparing and Giving Yourself an Injection of Betaseron

Medication Guide. This medication has been prescribed for your particular situation. Your doctor will tell you what dose of Betaseron to use, and that dose may change in the future. You should not change your dose without talking with your doctor.

If you have any questions, you should talk to your doctor. Betaseron is a type of medicine called an interferon. It is a protein that occurs naturally in the body. Betaseron is used to treat multiple sclerosis (MS) to slow or stop the damage that MS can cause and to keep the number of attacks (flares) of your MS under control. If someone gives you the injections, then you and/or the other person should be trained to give yourself the injections. You may need help training, consult the pharmacy where you purchased your Betaseron or your doctor.

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

Liver diseases

Problems with your thyroid gland

Blood conditions such as bleeding or bruising easily and anemia

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