

# Interferon Informed Consent

## Side effects of interferon alfa-2b

### What Is Interferon Alfa-2B?

Interferon alfa-2b belongs to a group of drugs called interferons. This medication works by stopping viruses from dividing and by triggering our immune system to kill invading pathogens or tumors. Interferon alfa-2b is made from human proteins. Interferons help your body's immune system respond to bacteria, viruses, cancer, or other invading substances.

Along with its needed effects, Interferon alfa-2b may cause some unwanted effects. Most of the side effects listed below probably won't occur, and if they do, may need medical attention.

### Primary Care Physician

Attached to this informed consent are two full pages of potential side effects and two pages of instructions for your primary care provider (PCP). Therefore, we require that you see your PCP regularly, first to draw some baseline labs, and then to monitor you and your blood labs on a regular basis for potential complications. We have included a note to your PCP so that he or she understands what it is we want him to do. Unfortunately, we cannot afford to police your compliance to follow-up with your PCP. Please tell your Interferon doctor immediately if you are unable to or choose not to follow-up with a PCP physician, so that your interferon treatments may be delayed or rescheduled for another time.

**FOR YOUR INFORMATION: We start most all patients on the lowest dose of interferon alfa-2b therapy,  $\leq 3$  million units per treatment, so reported side effects are usually at a minimum.** Side effects are reported 3% of the time for 1 million units, 83% for 3million units, and 100% for 5 million units.

Influenza-like symptoms (mainly **fever, headache, rigors/chills, myalgia, malaise, and fatigue**) were reported most often; usually beginning 3–6 hours after injection and may last 8 to 24 hours.

**Most side effects reported** during clinical trials were mild to moderate in severity and manageable. Some side effects were transient and most diminished with continued therapy. **These side effects were reversible within 72 hours** after interrupting or stopping therapy. In general, more severe toxicities were observed at higher doses.

- Using this medicine will not prevent your disease from spreading. Follow your doctor's instructions about how to prevent passing the disease to another person.
- Avoid drinking alcohol. It may increase your risk of liver damage. Avoid driving or hazardous activity until you know how this medicine will affect you. Your reactions could be impaired.

### Proper Use and Storage

Use a disposable needle and syringe only once. Store this medicine in the refrigerator. Do not freeze. After mixing the powder with a diluent, store this mixture in the refrigerator and use the first dose within 24 hours. Throw away any leftover medicine in a multi-dose vial 30 days after it is mixed.

**I certify that I have read or had read to me the contents of this form. I understand that there are risks and alternatives to interferon therapy and have had those explained to me. I agree to be under the care of a PCP before, during, & after treatment. If I feel uncomfortable for any reason, I have the right to refuse treatment.**

SIGNED: \_\_\_\_\_

WITNESS: \_\_\_\_\_ DATE: \_\_\_\_\_

## **SIDE EFFECTS THAT USUALLY DO NOT NEED MEDICAL ATTENTION**

Some side effects of interferon alfa-2b may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine.

### ***More Common***

- Acid or sour stomach
- bleeding gums
- blistering, crusting, irritation, itching, or reddening of the skin
- body aches or pain
- burning, crawling, itching, [numbness](#), prickling, "pins and needles", or tingling feelings
- change in taste, or bad, unusual, or unpleasant (after) taste
- cracked, dry, or scaly skin
- [hair loss](#) or thinning of the hair
- irritation in the mouth
- joint pain
- lack or loss of strength
- loss of memory
- muscle or bone pain
- pain or tenderness around the eyes and cheekbones
- poor concentration
- problems with memory
- redness and swelling of the gums
- stuffy or [runny nose](#)
- swollen joints

### ***Less Common***

- Abnormal ejaculation
- absent, missed, or irregular menstrual periods
- bleeding, burning, inflammation, itching, or pain at the injection site
- bone deformity
- burning, itching, and pain in the hairy areas, pus at the root of the hair
- burning, numbness, pain, or tingling in all fingers except smallest finger
- cold and clammy skin
- decrease in height
- decreased interest in sexual intercourse
- degenerative disease of the joint
- difficulty with moving or walking
- discoloration of the skin
- inability to have or keep an erection
- increased clear or white [vaginal discharge](#)
- increased sensitivity of the skin to sunlight
- itching or pain of the genital area
- leg cramps
- longer menstrual periods
- loss in sexual ability, desire, drive, or performance
- multiple swollen and inflamed skin lesions
- pain in the ankles or knees
- pain in the ribs
- pain, inflammation, or swelling in the calves, shoulders, or hands
- painful, red lumps under the skin, mostly on the legs
- [pelvic pain](#)
- rash with flat lesions or small raised lesions on the skin
- red or irritated eyes
- redness or swelling in the arms or legs
- redness, tenderness, itching, burning, or peeling of the skin
- severe sunburn
- shivering
- [skin rash](#), encrusted, scaly, and oozing small lumps under the skin
- small lumps under the skin
- soreness of the muscles
- stopping of menstrual bleeding
- swelling or redness in the joints
- tanning or blue-gray discoloration of the skin
- tearing of the eyes
- underactive reflexes
- unexpected menstrual bleeding

## SIDE EFFECTS THAT NEED IMMEDIATE MEDICAL ATTENTION

Although not all these side effects may occur, if they do occur they may need medical attention.

### *More Common*

- [Depression](#)
- difficult or labored breathing
- swelling or puffiness of the face
- tightness in the chest
- [weight loss](#)

### *Less Common*

- Back, leg, or stomach pains
- bleeding, tender, or enlarged gums
- bloody, black, or tarry stools
- bloody nose
- bloody or cloudy urine
- blurred vision
- change in personality
- changes in behavior
- chest pain, discomfort, or heaviness
- chills
- clay-colored stools
- confusion as to time, place, or person
- [constipation](#)
- cough producing mucus
- coughing or spitting up blood
- dark urine
- decreased urination
- [diarrhea](#)
- difficult or painful urination
- [dizziness](#), faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- drowsiness
- fainting
- fast, slow, pounding, irregular, or racing heartbeat or pulse
- feeling, seeing, or hearing things that are not there
- feeling that others are watching you or controlling your behavior
- feeling that others can hear your thoughts
- fever
- hallucinations
- [headache](#)
- [hearing loss](#)
- heavier menstrual periods
- [hives](#) or rash
- hoarseness or husky voice
- inability to speak
- increased thirst
- increased urination
- [indigestion](#)
- irritability
- itching, pain, redness, or swelling of the skin
- light-colored stools
- lightheadedness
- loss of appetite
- loss of consciousness
- loss of hearing
- lower back or side pain
- metallic taste
- muscle aches or cramps
- [nausea](#) or [vomiting](#)
- pale skin
- passing of gas
- pinpoint red spots on the skin
- [seizures](#)
- severe mood or mental changes
- severe stomach pain with [nausea and vomiting](#)
- slow speech
- sneezing
- sores, ulcers, or white spots on the lips or tongue or inside the mouth
- stiffness of the limbs
- stomach cramps, tenderness, or discomfort
- stomach pain, continuing
- [stomach upset](#)
- sweating
- swelling around the eyes
- swelling of the face, fingers, hands, ankles, feet, or lower legs
- swollen, painful, or tender lymph glands in the neck, armpit, or groin
- thoughts of hurting or killing oneself
- trouble sleeping
- unusual behavior
- unusual bleeding or bruising
- unusual tiredness or weakness
- weight gain
- yellowing of the eyes or skin

## **SEE YOUR PRIMARY CARE PROVIDER WHEN BEGINNING INTERFERON ALFA-2B THERAPY**

*And bring him or her this guide*

**Patients should be monitored closely with periodic clinical and laboratory evaluations by their PCP. Patients with persistently severe or worsening signs or symptoms of these conditions should be withdrawn from therapy. In many but not all cases, these disorders resolve after stopping interferon alfa-2b therapy.**

The following laboratory tests are recommended for all patients on INTRON A therapy, prior to beginning treatment and then periodically thereafter:

- Mild-to-moderate leukopenia and elevated serum liver enzyme (AST, a.k.a. SGOT) levels have been reported with intralesional administration of INTRON A; therefore, the monitoring of these laboratory parameters should be considered paramount.
  - Standard hematologic tests — including hemoglobin, complete and differential white blood cell counts, and platelet count.
  - Blood chemistries — electrolytes, liver function tests, and TSH.
  - Monitor hepatic function with serum bilirubin, ALT (alanine transaminase), AST (aspartate aminotransferase), alkaline phosphatase, and LDH (lactate dehydrogenase) at 2, 8 and 12 weeks following initiation of INTRON A, then every 6 months while receiving INTRON A.
  - Baseline chest X-rays have been suggested and should be repeated if clinically indicated.
  - Those patients who have preexisting cardiac abnormalities and/or are in advanced stages of cancer should have electrocardiograms taken prior to and during the course of treatment.
  - Permanently discontinue INTRON A for evidence of severe (Grade 3) hepatic injury or hepatic decompensation (Child-Pugh score >6 [class B and C]).
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- Serious eye problems. Interferon alfa-2b may cause eye problems that may lead to vision loss or blindness. You should have an eye exam before you start taking interferon alfa-2b. If you have eye problems or have had them in the past, you may need eye exams while taking interferon alfa-2b. Tell your healthcare provider or eye doctor right away if you have any vision changes while taking interferon alfa-2b.
  - Thyroid problems. Some people develop changes in the function of their thyroid. Symptoms of thyroid problems include: problems concentrating, feeling cold or hot all the time, changes in your weight, skin changes
  - Blood sugar problems. Some people may develop high blood sugar or diabetes. If you have high blood sugar or diabetes before starting interferon alfa-2b, talk to your healthcare provider before you take interferon alfa-2b.
  - Mental health problems and suicide. Interferon alfa-2b may cause you to develop mood or behavior problems that may get worse during treatment.
  - Infections. Some people who take interferon alfa-2b may get an infection.
  - Heart problems. Some people who take interferon alfa-2b may develop heart problems, including, low blood pressure, fast heart rate or abnormal heart beats, trouble breathing or chest pain, heart attacks or heart muscle problems (cardiomyopathy).
  - Stroke or symptoms of a stroke. Symptoms may include weakness, loss of coordination, and numbness. Stroke or symptoms of a stroke may happen in people who have some risk factors or no known risk factors for a stroke.
  - New or worsening autoimmune disease. Some people taking interferon alfa-2b develop autoimmune diseases (a condition where the body's immune cells attack other cells or organs in the body), including rheumatoid arthritis, systemic lupus erythematosus, sarcoidosis, and psoriasis. In some people who already have an autoimmune disease, the disease may get worse while on interferon alfa-2b.
  - You may need to have a chest X-ray or other tests if you develop fever, cough, shortness of breath, or other symptoms of a lung problem during treatment with interferon alfa-2b.

**Contraindications:** (continued)

**Known Drug Interactions/Contraindications:**

- telbivudine;
- theophylline; or
- zidovudine.

**You should not use the combination of interferon alfa-2b and ribavirin if you have:**

- severe kidney disease;
- a blood cell disorder such as thalassemia or sickle cell anemia;
- an allergy to interferons or ribavirin;
- if you are pregnant; or
- if you are a man and your sexual partner is pregnant.