

Treatment Agreement for: Interferon/Ribavirin Therapy

Interferon is given by injection under the skin, and some local pain or redness may occur at the site of the injection. The most common **side effects of interferon are flu-like symptoms, especially fever, fatigue, chills, nausea, headache, poor appetite, and muscle and joint pains.** These symptoms usually begin to occur two-eight hours after the injection. These side effects occur in nearly all patients within the first one-three doses of interferon, but these side effects often go away or decrease considerably over the duration of therapy. Patients taking daily or increased doses of interferon are likely to suffer more side effects. Taking Tylenol usually helps to lessen the side effects. Lethargy and fatigue can persist throughout therapy along with the above listed side effects.

Interferon treatment can also lead to decreases in the white blood cell count and in platelets (particles in the blood that help the blood clot). This is usually not serious and is quickly reversible once interferon treatment is stopped. **Because of the drops in blood count, it is crucial that you have your blood monitored on a regular basis.** If you cannot make your appointments, therapy will be discontinued. Also, temporary mild skin rashes may occur, and any pre-existing psoriasis or dermatitis may get worse while on treatment. Interferon treatment can also make pre-existing autoimmune diseases worse such as diabetes or rheumatoid arthritis.

Depression is often seen on interferon/ribavirin and on interferon alone. This depression can be severe and suicidal thoughts and even suicide attempts have been reported. **This occurs in both patients with and without previous psychiatric illness.**

Less common side effects that are seen with interferon treatment include diarrhea, vomiting, temporary hair loss, nervousness, dizziness, confusion, and increased irritability.

There are also several rare side effects that may occur while on interferon treatment. These include lung problems, such as irritation or pneumonia, and severe liver disease, possibly resulting

in death. Other rare effects include numbness or tingling in the hands and feet, visual disturbances, retinal hemorrhages (bleeding in the retina of the eye), and irregular heart rhythms. Diabetes mellitus and hyperglycemia (high blood sugar levels) have also been observed in patients on treatment with interferon.

Interferon treatment can lead to thyroid problems (either overactivity or underactivity of the thyroid) in a small percentage of patients. These thyroid problems can be controlled by medication, but the treatment may have to be life-long.

If at any time during treatment you are not able to tolerate these side effects, the interferon dose will be reduced, interrupted, or discontinued.

Ribavirin is taken in addition to interferon. It is taken orally and is generally well-tolerated. The most common side effect of ribavirin is **hemolytic anemia**. As a result there are less cells that carry oxygen to the tissues in your body. This condition is more common in older than in younger patients. The anemia is usually mild and improves with dose reduction of ribavirin. Anemia resolves once ribavirin therapy is discontinued. **You may experience some increased shortness of breath on exertion.** The anemia can be serious in patients who have kidney and/or heart problems. Heart and/or lung problems associated with anemia occur in a small percentage of patients on ribavirin therapy. **Frequent blood tests are crucial to evaluate this anemia.**

Other side effects that are common with ribavirin therapy include pruritis (localized or generalized itching), increased cough, and muscle pain. These effects are not considered serious and usually return to normal after the ribavirin is discontinued.

Side effects that occur rarely with ribavirin include gout (disease associated with increased amounts of uric acid in the blood and painful inflammation of the joints) and effects on the nervous system such as depression, nervousness, insomnia (difficulty in sleeping), and dizziness.

If at any time during treatment you are not able to tolerate these side effects, the ribavirin dose will be reduced, interrupted, or discontinued.

Studies in animals have shown that when ribavirin is given to pregnant females, malformations in the offspring or death of the developing embryo may occur.

This therapy must not be used by women or male partners of women who are or may become pregnant during therapy and during the six months after stopping therapy. It is important that both men and women on ribavirin use effective contraception or remain sexually abstinent during treatment and for six months after completion of treatment so that pregnancy does not occur.

During the treatment and follow-up periods, lab tests and medical visits are regular. These visits are very important in order to check your blood chemistry, pregnancy status, liver, heart, and thyroid function. Ongoing evaluation for depression and other mood disturbances while on treatment is vital.

Treatment Agreement:

_____ I have read the information on the side effects of pegylated interferon alfa 2a/ribavirin therapy, and desire to pursue this treatment.

_____ I have had a chance to ask questions regarding the risks and benefits of this therapy, and these questions have been answered to my satisfaction.

_____ I understand the importance and expectation of frequent follow up visits and blood draws to evaluate my tolerance and response to this therapy.

_____ I understand this therapy must not be used by women or male partners of women who are or may become pregnant during therapy and six months after stopping therapy. I have been counseled on the importance that both men and women on

ribavirin use 2 forms of birth control or remain sexually abstinent during treatment and for six months after completion of treatment so that pregnancy does not occur.

_____ I understand the importance of maintaining alcohol and drug abstinence and agree to do so. Periodic urine toxicology screening may be done while on treatment. I am aware of this and agreeable to this screening.

Signature of Patient

Date

Health Care Provider

Date