

Sovaldi® (Sofosbuvir), Ribavirin, & Peginterferon Treatment Agreement

If you are considering hepatitis C treatment, please read this treatment agreement carefully and be sure to ask any questions you may have before you sign the form.

The American Association for the Study of Liver Diseases (AASLD) and Infectious Disease Society of America (IDSA) developed hepatitis C guidelines for all genotypes (1 through 6) and encompassing re-treatment. The current FDA approved treatment for genotype 4 and some persons with genotype 3 is sofosbuvir in combination with peginterferon and ribavirin.

Treatment with sofosbuvir, ribavirin, and peginterferon requires 6 scheduled visits over a 6 month period if you undergo a 12-week treatment course.

PREGNANCY & BREASTFEEDING WARNING

Ribavirin can harm an unborn child or breastfeeding infant. A woman must not get pregnant and a man must not father a child while taking ribavirin or for 6 months after treatment. You must **use 2 forms of birth control** when you take ribavirin and for 6 months after your last dose.

Acceptable Birth Control Methods:

- Birth control pills or other hormone containing birth control
- Male or female condom
- Spermicides (creams, films, foams, gels, and/or suppositories)
- Diaphragm or cervical cap
- Intrauterine device (IUD), Today® vaginal sponge

Unacceptable Birth Control Methods:

- Rhythm method or withdrawal

HOW THE TREATMENT PROCESS WORKS

You will have blood and urine tests.

- These tests will include a pregnancy test for female patients of childbearing age. Urine pregnancy tests will be done monthly during clinic visits. If you are a woman and your treatment includes ribavirin it is recommended that you continue monthly home pregnancy testing for 6 months after treatment and notify your healthcare provider if you become pregnant. Female partners of males whose treatment includes ribavirin should do a monthly home pregnancy test during treatment and for 6 months after treatment completion and notify their health care provider if they become pregnant.
- Random drug and alcohol tests may be requested.
- At each visit, about 2-3 tubes of blood will be collected. Other examinations and tests may be done during the treatment if your provider feels there is a need.

Treatment Regimen:

_____ Sofosbuvir plus peginterferon and ribavirin will be given for 12 weeks if you have hepatitis C genotype 3, 4, 5, or 6 and are able to take peginterferon.

Your first three visits will be at the start of treatment (week 0) and weeks 2 and 4 after you begin taking the medications. After that, the visits will be once each month until you stop taking the medications. **You may need to see your primary care provider more frequently if you are having side effects or problems related to the treatment.**

You will have follow-up 3 months after treatment completion. If you have cirrhosis you should continue to have a liver ultrasound every six months and regular clinic visits.

TREATMENT MEDICATIONS AND SIDE EFFECTS

Sofosbuvir is a 400mg tablet. You will take sofosbuvir once daily by mouth with or without food. Store sofosbuvir at room temperature. If you miss a dose of sofosbuvir, take the missed dose as soon as you remember the same day. Do not take more than 1 tablet of sofosbuvir in a day. Take your next dose of sofosbuvir at your regular time the next day.

- Most common side effects are feeling tired, headache, nausea, trouble sleeping, and itching.

Tell your healthcare provider if you are taking any of the following medicines:

- Amiodarone (Cordarone[®], Nexterone[®], Pacerone[®])
- Carbamazepine (Carbatrol[®], Epitol[®], Equetro[®], Tegretol[®])
- Oxycarbazepine (Trileptal[®], Oxtellar XR[™])
- Phenytoin (Dilantin[®], Phenytek[®])
- Phenobarbital (Luminal[®])
- Rifabutin (Mycobutin[®])
- Rifampin (Rifadin[®], Rifamate[®], Rifater[®], Rimactane[®])
- Rifapentine (Priftin[®])
- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort
- Tipranavir (Aptivus[®])/Ritonavir

Ribavirin is a 200mg capsule or tablet. You will take ribavirin pills twice daily by mouth with food (dose is based on your weight). You should not miss/skip taking any pills. A common side effect is anemia. Anemia is a condition where the blood has a decreased number of red blood cells. This occurs more often in older persons taking ribavirin. Anemia can be serious in patients who have kidney problems. In patients who have coronary artery disease (narrowing of the blood vessels in the heart), anemia may make the problem worse, leading to chest pain or heart attack. If your provider believes you may have coronary artery disease, you will be tested for this and excluded from treatment if it is serious.

- Other common side effects include: headache, trouble sleeping, nausea, vomiting, weakness or lack of energy, loss of appetite, itching, cough, muscle pain, swelling and pain in your joints (gout), depression, nervousness, and dizziness.
- Studies in animals have shown when ribavirin is given to pregnant females, death of the developing embryo or birth of deformed baby animals may result. It is expected that similar results as seen in the animal studies could occur in humans.

Peginterferon is given with a short needle just under the skin of the abdomen. You may have pain and redness where the needle goes into the skin. You or a family member will be taught how to give the injection.

- Most common side effects are flu-like symptoms - fever, chills, body aches, feeling tired, nausea, headache, and poor appetite. These happen in almost all persons with the first 1 to 3 doses of peginterferon. After that they may go away or lessen, but sometimes these symptoms continue throughout the treatment course. Your white blood count and/or blood platelet count may decrease (go down) while you are taking peginterferon. White blood cells help protect the body from infections and platelets help your blood clot. You may also get a skin rash.
- Less common side effects are diarrhea, vomiting, temporary hair loss, nervousness, dizziness, confusion, and depression. Severe depression and, more rarely, suicide have been reported in persons treated with peginterferon. Some people taking peginterferon have had lung problems, pneumonia, stroke, heart attack, and liver problems; some people have died from these illnesses. Other side effects that can occur include bleeding in parts of your eye. A rarely reported side effect from peginterferon is visual loss.
- **If at any time during treatment you have a change/loss of vision, stop treatment immediately, notify your provider, and go to the emergency room.**
- A small percentage of patients treated with peginterferon have developed thyroid problems (either an overactive or underactive thyroid) which have required treatment. These types of thyroid problems can be controlled with medications but treatment may have to be lifelong.
- It is not known whether peginterferon can cause harm to a pregnant woman and/or the unborn child, or whether it can affect the ability of a woman to become pregnant or a man to father a child.

PLEASE NOTE:

You must let your medical, mental health, dental providers, and pharmacist(s) know that you are taking sofosbuvir, ribavirin, & peginterferon prior to starting any new medications. You must let your provider know about any new medications you are prescribed before starting them. This includes vitamins and other supplements.

Hepatitis C treatment should not cause pain that requires narcotic pain medication.

BENEFITS OF TREATMENT

In most cases, hepatitis C will respond to treatment as determined by a blood test that measures the presence and amount of hepatitis C in the blood. If you have no hepatitis C in your blood 12 weeks **after** the end of treatment, this is considered a “sustained virologic response” and in 99% of persons is a cure. Your chance of achieving a sustained virologic response depends on the hepatitis C genotype, how much hepatitis C virus you have in your blood at the beginning of treatment, any past treatment response, and how much liver damage you have had prior to treatment.

It is possible that you may develop some serious side effects, which will require you to stop the treatment. You may still benefit from treatment even if it does not get rid of your hepatitis C, as it may slow down the disease. You may choose to stop treatment at any time.

In Clinical Trials:

Persons with genotype 3 who were treatment-naïve and were given sofosbuvir in combination with peginterferon and ribavirin had a 97% response rate (39 patients studied).

Persons with genotype 4 who were treatment-naïve had a 96% response rate to sofosbuvir in combination with peginterferon and ribavirin for 12 weeks. Note, the number of genotype 4 patients in clinical trials was small (28 patients studied).

Few data from clinical trials are available for genotypes 5 and 6. Therefore if persons with genotype 5 or 6 need immediate treatment, daily sofosbuvir in combination with peginterferon and ribavirin therapy for 12 weeks is recommended by the AASLD and IDSA. No data supports use of a peginterferon-free treatment regimen for those with genotype 5 or 6.

WHOM TO CALL

If you have any questions about treatment, contact your primary care provider at _____.

TREATMENT AGREEMENT

To receive treatment, please review the following statements and initial beside the responses:

_____ I agree not to drink alcohol or use recreational drugs during the treatment.

_____ I have not abused alcohol or other substances (intravenous drugs, cocaine, prescription pain medications) within the last 6 months.

_____ I will tell my provider if I have any serious medical conditions (such as heart disease, high blood pressure, diabetes, high cholesterol, rheumatoid arthritis, or drug addiction), or psychiatric conditions (depression, history of suicide attempts, bipolar disorder, or psychosis). Failure to tell my provider about my medical and psychiatric conditions can have life-threatening consequences during this treatment.

_____ I am willing to visit the clinic and see a provider on a regular schedule for the entire length of the treatment. If I am unable to attend an appointment, I will let my provider know this ahead of time and I will reschedule my appointment.

_____ I understand that my treatment will be stopped if I cannot attend appointments as required to evaluate my health and well-being during treatment and the effectiveness of treatment.

_____ I will use 2 acceptable methods of birth control during treatment and for 6 months after I stop treatment (see lists, page 1).

_____ As a female, I understand that I cannot be pregnant or breastfeeding during the treatment and for 6 months after treatment. I understand that my treatment will be stopped if I become pregnant. _____ Not applicable, I am surgically sterile or post-menopausal.

_____ As a male taking ribavirin I understand that I should not father a child during treatment and for 6 months after treatment.

_____ If I have any problems with the medications or side effects that bother me, I will let my provider or nurse know right away.

_____ I understand that my hepatitis C may not respond to treatment.

_____ I understand that my provider can stop my treatment if the provider feels that stopping it is in the best interest of my health and welfare.

_____ I will do my best to take my medications as prescribed by my provider. If I am unable to do so, I will contact my provider.

_____ I will protect myself and others from hepatitis C by not sharing needles, toothbrushes, razors or nail clippers and covering cuts to prevent blood exposure.

My signature below means that I have read this treatment agreement and/or the meaning of the information has been explained to me. I agree to the treatment.

Patient's Name (PLEASE PRINT)

Patient's Signature

Date

Provider's Name & Title (PLEASE PRINT)

Provider's Signature

Date