

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

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**Family Medicine Provider:** \_\_\_\_\_

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. An FDA approved treatment for some persons with genotype 3, 4, 5 or 6 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 (must use 2):**

- 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 come to the clinic or see your primary care provider more frequently if you are having side effects or problems related to the treatment.**

You will have a liver clinic visit 3 months after treatment completion and then yearly (corresponding to your end of treatment date) for 5 years. If you have cirrhosis you should continue to have a liver ultrasound and alpha fetoprotein (AFP) cancer screening blood test 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<sup>®</sup>, Nexterone<sup>®</sup>, Pacerone<sup>®</sup>)
- Carbamazepine (Carbatrol<sup>®</sup>, Epitol<sup>®</sup>, Equetro<sup>®</sup>, Tegretol<sup>®</sup>)
- Oxcarbazepine (Trileptal<sup>®</sup>, Oxtellar XR<sup>®</sup>)
- Phenytoin (Dilantin<sup>®</sup>, Phenytek<sup>®</sup>)
- Phenobarbital (Luminal<sup>®</sup>); Primidone (Mysoline<sup>®</sup>)
- Rifabutin (Mycobutin<sup>®</sup>)
- Rifampin (Rifadin<sup>®</sup>, Rifamate<sup>®</sup>, Rifater<sup>®</sup>, Rimactane<sup>®</sup>)
- Rifapentine (Priftin<sup>®</sup>)
- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort
- Tipranavir (Aptivus<sup>®</sup>)

**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, shortness of breath, 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 the Liver Clinic, 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 Liver Clinic providers 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 called a “sustained virologic response” and means you no longer have hepatitis C. 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 95% response rate.

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).

For those with genotypes 5 and 6, sofosbuvir in combination with peginterferon and ribavirin for 12 weeks is an alternative treatment. In one clinical trial all 6 subjects with genotype 6 and the 1 subject with genotype 5 responded to treatment.

## **WHOM TO CALL**

If you have any questions about your treatment, contact the Liver Disease & Hepatitis Program @ 907-729-1560 or your primary care provider.

