

Epclusa® (Sofosbuvir/Velpatasvir) Treatment Agreement

Liver Disease & Hepatitis Program Providers: Brian McMahon, MD; Youssef Barbour, MD; Lisa Townshend-Bulson, FNP-C; Annette Hewitt, FNP-C; Prabhu Gounder, MD; Ellen Provost, DO; Stephen Livingston, MD; Timothy Thomas, MD

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.

On June 28, 2016 the FDA approved sofosbuvir combined with velpatasvir in one tablet (Epclusa®) for the treatment of hepatitis C genotypes 1-6.

Treatment length with Epclusa® is 12 weeks and requires 5 scheduled visits over 6 months.

PREGNANCY & BREASTFEEDING WARNING

It is not known if Epclusa® will harm an unborn or breastfeeding baby, so it is recommended that women do not get pregnant or breastfeed while taking this medicine.

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. A urine pregnancy test will be done monthly during a clinic visit.
- 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.

Liver Clinic Provider, select the appropriate treatment regimen and reason:

_____ Epclusa® will be given for 12 weeks if:

- You do not have cirrhosis.
- You have compensated (mild) cirrhosis.

Your first visit will be at the start of treatment. After that, visits will be once each month until you stop taking the medication.

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 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

Epclusa® is a fixed-dose combination tablet containing sofosbuvir 400mg and velpatasvir 100mg. You will take Epclusa® once daily by mouth with or without food. Store the medication at room temperature. If you miss a dose, take the missed dose as soon as you remember the same day. Do not take more than 1 tablet of Epclusa® in a day. Take your next dose at your regular time the next day.

- The most common side effects in clinical trials were headache (22%), feeling tired/fatigue (15%), and nausea (9%).

Tell your healthcare provider if you are taking any of the following medicines, as they are not recommended to be used with Epclusa® (this list is not all inclusive, medicines that are P-gp inducers and/or moderate to potent inducers of CYP2B6, CYP2C8, or CYP3A4 are not recommended):

- Co-administration of once daily medications for indigestion, heartburn, or stomach ulcers (Proton pump inhibitors) is not recommended. If medically necessary omeprazole (Prilosec®) no more than 20 mg daily is okay taken 4 hours after Epclusa®. In this case, Epclusa® should be taken with food. Esomeprazole (Nexium®), lansoprazole (Prevacid®), rabeprazole (Aciphex®), and pantoprazole (Protonix®) have not been studied with Epclusa®.
- Amiodarone (Cordarone®, Nexterone®, Pacerone®)
- Carbamazepine (Carbatrol®, Eptol®, Equetro®, Tegretol®)
- Efavirenz (ATRIPLA®)
- Oxycarbazepine (Trileptal®, Oxtellar XR®); Phenytoin (Dilantin®, Phenytek®); Phenobarbital (Luminal®); Primidone (Mysoline®)

- 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®) used in combination with ritonavir (Norvir®)
- Topotecan (Hycamtin®)

Tell your healthcare provider if you are taking any of the following medicines, as they require dose adjustment and/or monitoring:

- An antacid that contains aluminum or magnesium hydroxide (such as Roloids®, Maalox® and Mylanta®) must be taken 4 hours before or 4 hours after you take Epclusa®.
- Twice daily medicine for indigestion, heartburn, or stomach ulcers must be taken at the same time or 12 hours apart from Epclusa®. Famotidine (Pepcid AC®) no more than 40 mg twice daily is okay. Nizatidine (Axid®), cimetidine (Tagamet®), and ranitidine (Zantac®) have not been studied with Epclusa®.
- Digoxin (Lanoxin®)
- Regimens containing tenofovir disoproxil fumarate (DF) (ATRIPLA®, COMPLERA®, STRIBILD®, TRUVADA®, VIREAD®)
- Rosuvastatin (Crestor®) Do not exceed 10mg. Monitor for myopathy and rhabdomyolysis.
- Atorvastatin (Lipitor®) Monitor for myopathy and rhabdomyolysis.

PLEASE NOTE:

You must let your medical, mental health, dental providers, and pharmacist(s) know that you are taking Epclusa® 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 does 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 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:

The treatment response (cure) rate for Eplclusa® given for 12 weeks was 99% overall for persons with genotypes 1, 2, 4, 5, and 6 who were never treated before or were treated in the past with peginterferon and ribavirin with or without a protease inhibitor, who did not have cirrhosis, or had compensated (mild) cirrhosis (ASTRAL-1).

Persons with genotype 1a had a 98% response rate (ASTRAL -1).

Persons with genotype 1b had a 99% response rate (ASTRAL -1).

Persons with genotype 2 had a 99% response rate (ASTRAL-2).

Persons who were genotype 4 had a 100% response rate (ASTRAL -1).

Persons with genotype 5 had a 97% response rate (ASTRAL -1).

Persons with genotype 6 had a 100% response rate (ASTRAL -1).

The treatment response rate for Eplclusa® given for 12 weeks was 95% overall for persons with genotype 3 (ASTRAL-3).

For persons with genotype 3 who were treatment naïve without cirrhosis, the response rate was 98% (ASTRAL -3).

Persons with genotype 3 who were treatment experienced without cirrhosis had a response rate of 94% (ASTRAL -3).

Persons with genotype 3 who were treatment naïve (never before treated) and had compensated (mild) cirrhosis had a 93% response rate (ASTRAL -3).

Persons with genotype 3 who were treatment experienced with compensated (mild) cirrhosis had an 89% response rate (ASTRAL -3).

WHOM TO CALL

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

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 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).

_____ 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 for evaluation of my health and well-being during treatment and the effectiveness of treatment.

_____ As a female taking Epclusa®, I will not get pregnant or breastfeed while on treatment. I understand that my treatment will be stopped if I become pregnant.

_____ Not applicable, I am surgically sterile or post-menopausal.

_____ 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 treatment.

Patient's Name (PLEASE PRINT)

Patient's Signature

Date

Provider's Name (PLEASE PRINT)

Provider's Signature

Date