

## Epclusa® (Sofosbuvir/Velpatasvir) Information Packet

**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 begin treatment.

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

### **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.

### **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 your providers know about any new medications you are prescribed before starting them. This includes vitamins and other supplements.

If you have ever had hepatitis B infection, the virus could become active again during or after taking Epclusa®. You will have blood tests to check for hepatitis B infection before starting treatment (HBsAg, HBcAb). If you have hepatitis B or are HBcAb or HBsAg positive you will have HBV DNA levels checked before and while on treatment.

### **HOW THE TREATMENT PROCESS WORKS**

You will have an appointment monthly while you are taking the medication.

- At each visit blood will be collected.
- A monthly pregnancy test will be done for female patients of childbearing potential.
- Random drug and alcohol tests may be requested.
- Other tests may be done during the treatment if your provider feels there is a need.

Three months after completing treatment you will have an appointment to test for cure of hepatitis C.

### **IF YOU HAVE ADVANCED FIBROSIS OR CIRRHOSIS**

- **You should continue to have a liver ultrasound and alpha fetoprotein (AFP) cancer screening blood test every six months.**

**Provider, select the appropriate treatment regimen and reason:**

\_\_\_\_ Epclusa® will be given for 12 weeks if you do not have cirrhosis -OR- you have compensated (mild) cirrhosis.

\_\_\_\_ Epclusa® will be given for 24 weeks if you have genotype 1, 2, 3, 4, 5 or 6 hepatitis C with decompensated cirrhosis and are ribavirin ineligible.

## **TREATMENT MEDICATIONS AND SIDE EFFECTS**

**Epclusa**<sup>®</sup> is a fixed-dose combination tablet containing sofosbuvir 400mg and velpatasvir 100mg. You will take Epclusa<sup>®</sup> 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<sup>®</sup> 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%) and feeling tired/fatigue (15%).**

Tell your healthcare provider if you are taking any of the following medicines, as they are not recommended to be used with Epclusa<sup>®</sup> (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<sup>®</sup>) no more than 20 mg daily is okay taken 4 hours after Epclusa<sup>®</sup>. In this case, Epclusa<sup>®</sup> should be taken with food. Esomeprazole (Nexium<sup>®</sup>), lansoprazole (Prevacid<sup>®</sup>), rabeprazole (Aciphex<sup>®</sup>), and pantoprazole (Protonix<sup>®</sup>) have not been studied with Epclusa<sup>®</sup>.
- Amiodarone (Cordarone<sup>®</sup>, Nexterone<sup>®</sup>, Pacerone<sup>®</sup>). [Provider note: If there is no alternative treatment option refer to full prescribing information and counsel patients about risk of symptomatic bradycardia (near-fainting, fainting, dizziness or lightheadedness, extreme tiredness, weakness, excessive tiredness, shortness of breath, chest pain, confusion, or memory problems)].
- Carbamazepine (Carbatrol<sup>®</sup>, Epitol<sup>®</sup>, Equetro<sup>®</sup>, Tegretol<sup>®</sup>)
- Efavirenz (ATRIPLA<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>) used in combination with ritonavir (Norvir<sup>®</sup>)
- Topotecan (Hycamtin<sup>®</sup>)

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<sup>®</sup>, Maalox<sup>®</sup> and Mylanta<sup>®</sup>) must be taken 4 hours before or 4 hours after you take Epclusa<sup>®</sup>.
- Twice daily medicine for indigestion, heartburn, or stomach ulcers must be taken at the same time or 12 hours apart from Epclusa<sup>®</sup>. Famotidine (Pepcid AC<sup>®</sup>) no more than 40

mg twice daily is okay. Nizatidine (Axid®), cimetidine (Tagamet®), and ranitidine (Zantac®) have not been studied with Eplusa®.

- 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.
- Warfarin (Coumadin®) Fluctuations of INR values may occur. Frequent monitoring of INR during and post-treatment is recommended.

### **BENEFITS OF TREATMENT**

If you have no hepatitis C in your blood 12 weeks **after** the end of treatment, you are cured. Your chance of cure depends on the hepatitis C genotype, how much virus you have in your blood at the beginning of treatment, any past treatment response, how much liver damage you have had prior to treatment, and taking the medication every day.

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.

### **In Clinical Trials:**

The treatment response (cure) rate for Eplusa® given for 12 weeks was 99% overall for persons with genotypes 1, 2, 3, 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); those 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 Eplusa® given for 12 weeks was 95% overall for persons with genotype 3 (ASTRAL-3).

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).

In persons with decompensated cirrhosis, the overall treatment response (cure) rate for Epclusa® given for 24 weeks was 86%. Those with genotype 1 had a 92% response rate. Persons with genotype 3 had a 50% (6/12). Eight persons in this study had genotype 4, no persons had genotype 2 or 5, and 1 person had genotype 6 (ASTRAL-4).

### **To take care of your liver and prevent the spread of hepatitis C**

- Do not share needles or other drug works, toothbrushes, razors, or nail clippers.
- Cover cuts to prevent blood exposure.
- Only get a tattoo if the equipment and ink used is sterile (such as at a commercial, regulated tattoo studio).
- Practice safe sex.
- Do not drink alcohol or use drugs because these hurt the liver.

**WHOM TO CALL** If you have any questions, contact your primary care provider.

**Epclusa® Treatment Medication:** Take ONE tablet of Epclusa® by mouth daily, with or without food.

- 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®.
- Once daily medications for indigestion, heartburn, or stomach ulcers must be taken 4 hours after Epclusa®. In this case, Epclusa® should be taken with food. Omeprazole (Prilosec®) no more than 20 mg daily is okay. Esomeprazole (Nexium®), lansoprazole (Prevacid®), rabeprazole (Aciphex®), and pantoprazole (Protonix®) have not been studied with Epclusa®.
- Do not take supplements or tea containing St. John's wort while taking Epclusa®.

Pick up refills for **Epclusa®** after monthly appointments.

**\*\*\*For any emergencies after normal business hours, please go to the Emergency Room. Make sure any healthcare provider you see knows you are on treatment. Carry a list of your medicines with you.**

For more information on managing side effects visit our website at <http://anthc.org/hep>