

Vosevi® (Sofosbuvir/Velpatasvir/Voxilaprevir) Information Packet

Liver Disease & Hepatitis Program Providers:

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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 begin treatment.

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

PREGNANCY & BREASTFEEDING WARNING

It is not known if Vosevi® 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 medical, mental health, dental providers, and pharmacist(s) know that you are taking Vosevi® before 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.

If you have ever had hepatitis B infection, the virus could become active again during or after taking Vosevi®. 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. You will then be seen yearly (corresponding to your end of treatment date) for the next 5 years. You may need to see your primary care provider during treatment if you have any other health concerns.

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.**
- You will have an additional appointment in Liver Clinic 6 months after completing treatment.

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

___ Vosevi® will be given for 12 weeks:

- You do not have cirrhosis or have compensated cirrhosis and were previously treated with an NS5A inhibitor-containing regimen.
- You do not have cirrhosis or have compensated cirrhosis and have genotype 1a or 3 previously treated with a sofosbuvir-containing regimen without an NS5A inhibitor.

TREATMENT MEDICATIONS AND SIDE EFFECTS

Vosevi® is a fixed-dose combination tablet containing sofosbuvir 400mg, velpatasvir 100mg, and voxilaprevir 100mg. You will take Vosevi® once daily by mouth with food. Store the medication at room temperature. Do not skip any doses. If you miss a dose, take the missed dose as soon as you remember on the same day. Do not take more than 1 tablet of Vosevi® 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 (≈18%), diarrhea (≈14%), and nausea (≈ 13%).**

Tell your healthcare provider if you are taking the following medication, as it is contraindicated with Vosevi®.

- Rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)

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

- Amiodarone (Cordarone®, Nexterone®, Pacerone®). [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®, Epitol®, Equetro®, Tegretol®)
- Atazanavir (Reyataz®, Evotaz™); Lopinavir (Kaletra®)
- Cyclosporine (Sandimmune®, Neoral®, Restasis™, Gengraf®, Graftin®)
- Efavirenz (ATRIPLA®, Sustiva®)

- Oxcarbazepine (Trileptal[®], Oxtellar XR[®]); Phenytoin (Dilantin[®], Phenytek[®]); Phenobarbital (Luminal[®]); Primidone (Mysoline[®])
- Rifabutin (Mycobutin[®]); Rifapentine (Priftin[®])
- Rosuvastatin (Crestor[®]); Pitavastatin (Livalo[®])
- 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[®]), Mitoxantrone (Novantrone[®]), Imatinib (Gleevec[®]), Irinotecan (Camptosar[®]), Lapatinib (Tykerb[®])
- Methotrexate (Otrexup[™], Rasuvo[®], Rheumatrex Dose Pack[®], Trexall[™], Xatmep[™])
- Sulfasalazine (Azulfidine[®], Sulfazine[®])

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

- Co-administration of once daily medications for indigestion, heartburn, or stomach ulcers (Proton pump inhibitors) such as omeprazole (Prilosec[®]) no more than 20 mg daily, is okay to take with Vosevi[®]. Esomeprazole (Nexium[®]), lansoprazole (Prevacid[®]), rabeprazole (Aciphex[®]), and pantoprazole (Protonix[®]) have not been studied with Vosevi[®].
- 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 Vosevi[®].
- Twice daily medicine for indigestion, heartburn, or stomach ulcers must be taken at the same time or 12 hours apart from Vosevi[®]. Famotidine (Pepcid AC[®]) no more than 40 mg twice daily is okay. Nizatidine (Axid[®]), cimetidine (Tagamet[®]), and ranitidine (Zantac[®]) have not been studied with Vosevi[®].
- Pravastatin (Pravachol[®]). Do not exceed 40mg. Monitor for myopathy and rhabdomyolysis.
- Atorvastatin (Lipitor[®]); Fluvastatin (Lescol[®]); Lovastatin (Mevacor[®]); or Simvastatin (Zocor[®]). Use lowest approved dose and monitor for myopathy and rhabdomyolysis.
- Warfarin (Coumadin[®]) Fluctuations of INR values may occur. Frequent monitoring of INR during and post-treatment is recommended.
- Digoxin (Lanoxin[®])
- Dabigatran etexilate (Pradaxa[®])
- Regimens containing tenofovir disoproxil fumarate (DF) (ATRIPLA[®], COMPLERA[®], STRIBILD[®], TRUVADA[®], VIREAD[®])

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 Studies and Clinical Trials:

The treatment response (cure) rate for Vosevi® given for 12 weeks was 96% overall for persons with genotypes 1, 2, 3, 4, 5, or 6 who were treated in the past with an NS5A inhibitor, who did not have cirrhosis, or had compensated (mild) cirrhosis (POLARIS-1).

- Persons with genotype 1a without cirrhosis had a 97% (66/68) response and those with cirrhosis had a 94% (31/33) response rate.
- Persons with genotype 1b with or without cirrhosis had a 100% (45/45) response rate.
- Persons with genotype 2 without cirrhosis had a 100% (5/5) response rate. There were no persons with genotype 2 and cirrhosis in the study.
- Persons with genotype 3 without cirrhosis had a 100% (22/22) response and those with cirrhosis had a 93% (52/56) response rate.
- Persons with genotype 4 had a 91% (20/22) response rate. Both patients who were not cured had cirrhosis.
- Persons with genotype 5 had a 100% (1/1) response rate.
- Persons with genotype 6 had a 100% (6/6) response rate.

Vosevi® was given for 12 weeks to persons with genotype 1a or 3 previously treated with a sofosbuvir-containing regimen without an NS5A inhibitor (POLARIS-4).

- The treatment response (cure) rate for persons with genotype 1a without cirrhosis was 100% (37/37). For those with cirrhosis the response rate was 94% (16/17).
- The treatment response (cure) rate for persons with genotype 3 without cirrhosis was 96% (22/23). For those with cirrhosis the response rate was 94% (29/31).

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 call the Liver Disease & Hepatitis Program @ 907-729-1560 or your primary care provider.

Vosevi® (sofosbuvir 400mg, velpatasvir 100mg, voxilaprevir 100mg) Treatment Medication

Take ONE tablet of Vosevi® by mouth daily, with food.

The generic name for **Vosevi®** is **sofosbuvir 400mg/velpatasvir 100mg/voxilaprevir 100mg.**

- 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 Vosevi®.
- Twice daily medicine for indigestion, heartburn, or stomach ulcers must be taken at the same time or 12 hours apart from Vosevi®. Famotidine (Pepcid AC®) no more than 40 mg twice daily is okay. Nizatidine (Axid®), cimetidine (Tagamet®), and ranitidine (Zantac®) have not been studied with Vosevi®.
- Once daily medications for indigestion, heartburn, or stomach ulcers must be taken at the same time as Vosevi®. Omeprazole (Prilosec®) no more than 20 mg daily is okay. Esomeprazole (Nexium®), lansoprazole (Prevacid®), rabeprazole (Aciphex®), and pantoprazole (Protonix®) have not been studied with Vosevi®.
- Do not take supplements or tea containing St. John’s wort while taking Vosevi®.

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

For Specialty Pharmacy refills, call: _____

On these dates: _____

Call Liver Clinic (907-729-1560) if you feel you are having any significant side effects while taking these medications or have any other questions about treatment.

*****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>