# GET **STARTED**





### What is sofosbuvir/velpatasvir?

Sofosbuvir/velpatasvir is a prescription medicine used to treat adults with chronic (lasting a long time) hepatitis C (Hep C) genotype 1, 2, 3, 4, 5, or 6 infection with or without cirrhosis (compensated). In those with advanced cirrhosis (decompensated), sofosbuvir/velpatasvir is used with ribavirin.

# WELCOME TO HEPATITIS C TREATMENT WITH THE AUTHORIZED GENERIC OF EPCLUSA®

By starting treatment with sofosbuvir/velpatasvir (SOF/VEL), the authorized generic of EPCLUSA®, you and your Hep C Specialist have chosen a breakthrough Hep C treatment.

In the following pages, you will learn about treatment with SOF/VEL so you'll be ready to go on day one. Make sure to keep this brochure handy because it may help you get organized as you begin taking SOF/VEL. It can also be used as a quick reference throughout your treatment.

# WHAT IS AN AUTHORIZED GENERIC?

An authorized generic is the same drug product as a brand-name drug product, with all the same ingredients, but it does not have the brand name on its label and may use different packaging. The color and marking on the pills may also be different from the brand-name drug.

Authorized generic medications often reduce patient out-of-pocket costs and may make treatment accessible for more patients. Total savings will be determined by your healthcare insurance coverage.

### It's time to get started.

For more information about sofosbuvir/velpatasvir,

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Call 1-877-404-3157

Visit www.hepcauthorizedgenerics.com

Sofosbuvir and Velpatasvir 400 mg/100 mg tablets



## What is the most important information I should know about sofosbuvir/velpatasvir?

Sofosbuvir/velpatasvir can cause serious side effects, including:

• Hepatitis B virus reactivation: Before starting sofosbuvir/velpatasvir treatment, your healthcare provider will do blood tests to check for hepatitis B infection. If you have ever had hepatitis B, the hepatitis B virus could become active again during and after treatment with sofosbuvir/velpatasvir. This may cause serious liver problems including liver failure and death. If you are at risk, your healthcare provider will monitor you during and after taking sofosbuvir/velpatasvir.

## A PROVEN TREATMENT

SOF/VEL has been proven to effectively treat all six main Hep C genotypes with a one-pill, once-a-day treatment regimen for the majority of patients.\*



In clinical studies, SOF/VEL had an overall cure rate of 98% in patients with genotypes 1, 2, 3, 4, 5, or 6

Cure means the Hep C virus is not detected in the blood when measured three months after treatment is completed.

A one-pill, once-a-day treatment regimen for most patients.\*

\*Sofosbuvir/velpatasvir with ribavirin is recommended for patients with advanced cirrhosis (decompensated).† If you take sofosbuvir/velpatasvir with ribavirin, you should also read the ribavirin Medication Guide for important pregnancy-related information.

†Advanced cirrhosis (decompensated) is when the liver is extensively scarred and can no longer do its job effectively.

> Please see page 5 to learn more about sofosbuvir/velpatasvir clinical study results.

### What should I tell my healthcare provider before taking sofosbuvir/velpatasvir?

• Tell your healthcare provider about all of your medical conditions, including if you have ever had hepatitis B infection or liver problems other than hepatitis C infection; if you have kidney problems or are on dialysis; if you have HIV; or if you are pregnant or breastfeeding, or plan to become pregnant or breastfeed. It is not known if sofosbuvir/velpatasvir will harm your unborn baby or pass into your breast milk. If you take sofosbuvir/ velpatasvir with ribavirin, you should also read the ribavirin Medication Guide for important pregnancy-related information.

> Sofosbuvir and Velpatasvir 400 mg/100 mg tablets

# Sofosbuvir/Velpatasvir



You've made the important decision to seek treatment with SOF/VEL. Live Support Path navigators can help you understand your insurance coverage and explain potential cost-saving options.

Call a Support Path navigator today at

1-855-7-MYPATH

(1-855-769-7284)



Support Path navigators will start by researching and explaining what your health insurance benefits are.

This is called a benefits investigation.



They'll also explain the insurance approval process.

SOF/VEL is considered a specialty drug so your insurance company needs to approve your prescription before you can receive it.

Remember, Support Path navigators are here to help you get started and at any time during the insurance-approval process.

# Sofosbuvir/Velpatasvir

## CO-PAY COUPON

may help reduce the out-of-pocket cost of treatment for eligible patients

Call a Support Path navigator or go to **www.mysupportpath.com/patients** to find out if you are eligible and for full terms and conditions.



Eligible patients pay as little as

\$5 per co-pay.\*

\*Restrictions apply.

You are not eligible if you are enrolled in a government healthcare prescription drug program such as Medicaid or Medicare Part D (including when you are in the coverage gap known as the "donut hole").

Even if you are not eligible for the co-pay coupon, call a Support Path navigator to learn about other financial resources that may be available to you.

# **JUST 1 PILL, ONCE A DAY FOR 12 WEEKS**

In clinical studies, SOF/VEL has been shown to have high cure rates in patients with Hep C GT 1-6 with or without compensated cirrhosis, with just 12 weeks of treatment—regardless of prior Hep C treatment experience. Cure means the Hep C virus is not detected in the blood when measured three months after treatment is completed.

**Genotype 1, 2, 3, 4, 5, or 6 patients** with or without compensated cirrhosis

Genotype	Dosing	Cure Rate
1		98%*
2		<b>99</b> %†
3	One Pill Per Day	95%‡
4	12 Weeks of Treatment	100%*
5		97%*
6		100%*

This information does not apply to patients with advanced cirrhosis (decompensated).§ Please see page 8 for information on this patient type.



## What should I tell my healthcare provider before taking sofosbuvir/velpatasvir? (continued)

• Tell your healthcare provider and pharmacist about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Sofosbuvir/velpatasvir and certain other medicines may affect each other, or may cause side effects.

<sup>\*</sup>In a study of 740 patients with genotype 1, 2, 4, 5, or 6 Hep C, with or without prior Hep C treatment, and with or without cirrhosis (compensated), patients received either sofosbuvir/velpatasvir or placebo for 12 weeks.

<sup>†</sup>In a study of 266 patients with genotype 2 Hep C, with or without prior Hep C treatment, and with or without cirrhosis (compensated), patients received either sofosbuvir/velpatasvir or sofosbuvir + ribavirin for 12 weeks.

<sup>&</sup>lt;sup>‡</sup>In a study of 552 patients with genotype 3 Hep C, with or without prior Hep C treatment, and with or without cirrhosis (compensated), patients received either sofosbuvir/velpatasvir for 12 weeks or sofosbuvir + ribavirin for 24 weeks.

<sup>§</sup>Advanced cirrhosis (decompensated) is when the liver is extensively scarred and can no longer do its job effectively.

# SOFOSBUVIR/VELPATASVIR: EFFECTIVE IN A BROAD RANGE OF PATIENTS

People who have both Hep C and HIV-1 and people who have Hep C and advanced cirrhosis (decompensated)\* can be treated with the SOF/VEL regimen

**For people with both Hep C and HIV-1,** the recommended SOF/VEL treatment length is 12 weeks for all genotypes, the same as for those without HIV-1.

It is important to talk with your healthcare provider about your HIV antiretroviral medicine(s) to understand potential interactions with SOF/VEL.

For people with advanced cirrhosis\* and Hep C genotype 1–6,

SOF/VEL plus ribavirin provides an all-oral treatment option with just 12 weeks of therapy.

If you have any questions about your treatment regimen, it is important to talk to your Hep C Specialist.

If you take SOF/VEL with ribavirin, you should also read the ribavirin Medication Guide for important pregnancy-related information.

\*Advanced cirrhosis (decompensated) is when the liver is extensively scarred and can no longer do its job effectively.

# LIVE NURSE SUPPORT IS HERE IF YOU NEED IT



### Sometimes you need a little extra help.

Of course, your Hep C Specialist is always your first and best resource for information. But our live nurse support is also available to answer questions you may have.

### Some commonly asked questions include:

- What are the most common side effects with SOF/VEL?
- How will I know if SOF/VEL is working?
- What do I do if I miss a dose of SOF/VEL?

Call 1-877-404-3157

FOR

**Live Nurse Support** 

# What are the possible side effects of sofosbuvir/velpatasvir? Serious side effects may also include:

• Slow heart rate (bradycardia): Sofosbuvir/velpatasvir, when taken with amiodarone (Cordarone®, Nexterone®, Pacerone®), a medicine used to treat certain heart problems, may cause slow heart rate. In some cases slow heart rate has led to death or the need for a pacemaker when amiodarone is taken with medicines containing sofosbuvir. Get medical help right away if you take amiodarone with sofosbuvir/velpatasvir and get any of the following symptoms: fainting or near-fainting, dizziness or lightheadedness, not feeling well, weakness, extreme tiredness, shortness of breath, chest pains, confusion, or memory problems.

# **About Treatment**

# **HOW SHOULD YOU TAKE SOFOSBUVIR/VELPATASVIR?**

- Take SOF/VEL exactly as your healthcare provider tells you to take it. Do not change your dose unless your healthcare provider tells you to
- Do not stop taking SOF/VEL without first talking with your healthcare provider
- Take 1 SOF/VEL tablet each day
- Take SOF/VEL with or without food
- It is important that you do not miss or skip doses of SOF/VEL during treatment
- If you take too much of SOF/VEL, call your healthcare provider or go to the nearest hospital emergency room right away

Now that you understand how you should take SOF/VEL, you might want to use the box below to set a specific time or routine for taking your medicine every day.

If you take SOF/VEL with ribavirin, you should also read the Medication Guide for ribavirin including dosing information.



Take 1 SOF/VEL tablet each day Take SOF/VEL with or without food

I will take my SOF/VEL tablet every day at AM/PM when I

# **STAYING ON TRACK** WITH YOUR TREATMENT

If you take the time to create a routine at the beginning of your SOF/VEL treatment, it may be easier for you to stay on track for the next 12 weeks.

It's important that you take SOF/VEL every day. Here are some suggestions that may help you remember:



Set your alarm clock or phone alarm as a daily reminder to take your medicine every day



Keep SOF/VEL with your other daily medications



Leave a reminder note where you'll be sure to see it (like the bathroom mirror, your pillow, or next to your toothbrush)

With hepatitis C treatment, the most important thing a person can do when trying to achieve cure is to take their medication exactly as instructed by their Hep C Specialist.

What are the possible side effects of sofosbuvir/velpatasvir? (continued)

The most common side effects of sofosbuvir/velpatasvir include headache and tiredness. Tell your healthcare provider if you have any side effect that bothers you or does not go away.

# TAKING SOFOSBUVIR/VELPATASVIR **AND OTHER MEDICINES**

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. This is because SOF/VEL and certain other medicines may affect each other, or may cause side effects.

If you take warfarin, it is important to tell your healthcare provider.

It is also particularly important to tell your healthcare provider if you take any of the following medicines for:

Ш	Indigestion, Heartburn, or Stomach Ulcers (Acid Reducing Agents)
	Please see next page
Ш	Abnormal Heart Rhythms (Antiarrhythmics) amiodarone (Cordarone®, Nexterone®, Pacerone®); digoxin (Lanoxin®)
	Cancer (Anticancer Agents) topotecan (Hycamtin®)
	Seizures or Epilepsy (Anticonvulsants)
	carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®); oxcarbazepine (Trileptal®, Oxtellar XR®); phenytoin (Dilantin®, Phenytek®); or phenobarbital (Luminal®)
	HIV (Antiretrovirals)
	Any medicines containing tenofovir disoproxil fumarate including: ATRIPLA®1, COMPLERA®2, STRIBILD®3, TRUVADA®4, VIREAD®5; efavirenz (Sustiva®); tipranavir (Aptivus®) used in combination with ritonavir (Norvir®)
	Tuberculosis (Antimycobacterials)
	rifabutin (Mycobutin®); rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®); rifapentine (Priftin®)
	Cholesterol (Statins)
	rosuvastatin (Crestor®); atorvastatin (Lipitor®)
	Other Conditions (Herbal Supplements)
	St. John's wort or a product that contains St. John's wort

Before taking SOF/VEL with medicines for gas, indigestion, heartburn, or stomach ulcers, be sure to talk with your healthcare provider.

Common Brand Names	Recommendation
Mylanta® Maalox TC® Other antacids containing aluminum or magnesium hydroxide	Take 4 hours before or 4 hours after SOF/VEL.
Pepcid® (famotidine) Tagamet® (cimetidine) Axid® (nizatidine) Zantac® (ranitidine)	Talk to your healthcare provider about the dose and how to take it. For example, famotidine can be taken at the same time as SOF/VEL or 12 hours apart at a dose that does not exceed 40 mg twice daily.
Prilosec® (omeprazole) Prevacid® (lansoprazole) Nexium® (esomeprazole) AcipHex® (rabeprazole) Protonix® (pantoprazole)	Taking SOF/VEL with Prilosec® (omeprazole) or other proton pump inhibitors is not recommended. If it is considered medically necessary to take both medicines, SOF/VEL should be taken with food, 4 hours before Prilosec® 20 mg is taken. Taking SOF/VEL with other proton pump inhibitors has not been studied.

<sup>&</sup>lt;sup>1</sup>efavirenz/emtricitabine/tenofovir disoproxil fumarate; <sup>2</sup>emtricitabine/rilpivirine/tenofovir disoproxil fumarate; <sup>3</sup>elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate; <sup>4</sup>emtricitabine/tenofovir disoproxil fumarate; <sup>5</sup>tenofovir disoproxil fumarate



# What is the most important information I should know about sofosbuvir/velpatasvir?

Sofosbuvir/velpatasvir can cause serious side effects, including:

• Hepatitis B virus reactivation: Before starting sofosbuvir/velpatasvir treatment, your healthcare provider will do blood tests to check for hepatitis B infection. If you have ever had hepatitis B, the hepatitis B virus could become active again during and after treatment with sofosbuvir/velpatasvir. This may cause serious liver problems including liver failure and death. If you are at risk, your healthcare provider will monitor you during and after taking sofosbuvir/velpatasvir.

# UNDERSTANDING COMMON SIDE EFFECTS

With SOF/VEL, the most common side effects seen in clinical trials include headache and tiredness.



When SOF/VEL is used with ribavirin for those with advanced cirrhosis, common side effects also include anemia, nausea, insomnia, and diarrhea.

Tell your healthcare provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of SOF/VEL. For more information, ask your healthcare provider or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.



NOTES:		

# For more information call: **1-877-404-3157** or visit **hepcauthorizedgenerics.com**

Please see Important Facts about sofosbuvir/velpatasvir including **Important Warning** on page 12.

## Sofosbuvir and Velpatasvir 400 mg/100 mg tablets

(soe-fos'-bue-vir) (vel-pat'-as-vir)

### MOST IMPORTANT INFORMATION ABOUT SOFOSBUVIR/VELPATASVIR

Sofosbuvir/velpatasvir can cause serious side effects, including:

**Hepatitis B virus reactivation:** Before starting treatment with sofosbuvir/velpatasvir, your healthcare provider will do blood tests to check for hepatitis B infection. If you have ever had hepatitis B, the hepatitis B virus could become active again during or after treatment with sofosbuvir/velpatasvir. This may cause serious liver problems including liver failure and death. Your healthcare provider will monitor you if you are at risk for hepatitis B reactivation during and after you stop taking sofosbuvir/velpatasvir.

### ABOUT SOFOSBUVIR/VELPATASVIR

Sofosbuvir/velpatasvir is a prescription medicine used to treat adults and children 6 years of age and older or weighing at least 37 lbs (17 kg) with chronic (lasting a long time) hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection with or without cirrhosis (compensated). In those with advanced cirrhosis (decompensated), sofosbuvir/ velpatasvir is used with ribavirin.

### **POSSIBLE SIDE EFFECTS** OF SOFOSBUVIR/VELPATASVIR

Sofosbuvir/velpatasvir can cause serious side effects, includina:

- Those in the "Most Important Information about sofosbuvir/velpatasvir" section.
- Slow heart rate (bradycardia): Sofosbuvir/velpatasvir, when taken with amiodarone (Cordarone®. Nexterone®. Pacerone®), a medicine used to treat certain heart problems, may cause slow heart rate, which in some cases has led to death or the need for a pacemaker when amiodarone is taken with medicines containing sofosbuvir. Get medical help right away if you take amiodarone with sofosbuvir/velpatasvir and get any of the following symptoms:
- fainting or near-fainting extreme tiredness
- dizziness or
- shortness of breath
- lightheadedness
- chest pains
- not feeling well weakness
- confusion
- memory problems

The most common side effects of sofosbuvir/velpatasvir include headache and tiredness. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of sofosbuvir/ velpatasvir. For more information, ask your healthcare provider or pharmacist. You may report side effects to FDA at 1-800-FDA-1088.

### **IMPORTANT FACTS**

This is only a brief summary of important information about sofosbuvir/velpatasvir and does not replace talking to your healthcare provider about your condition and your treatment.

#### BEFORE TAKING SOFOSBUVIR/VELPATASVIR

Tell your healthcare provider about all of your medical conditions, including if you:

- have ever had hepatitis B virus infection
- have liver problems other than hepatitis C infection
- have kidney problems or you are on dialysis
- have HIV-1 infection
- are pregnant or breastfeeding, or plan to become pregnant or breastfeed
  - If you take sofosbuvir/velpatasvir with ribavirin, you should also read the ribavirin Medication Guide for important pregnancy-related information.

### Tell your healthcare provider about all the medicines you take:

- Keep a list that includes all prescription and over-the-counter medicines, vitamins, and herbal supplements, and show it to your healthcare provider.
- Sofosbuvir/velpatasvir and certain medicines may affect each other, or cause side effects.

#### **GET MORE INFORMATION**

- This is only a brief summary of important information about sofosbuvir/velpatasvir. Talk to your healthcare provider or pharmacist to learn more.
- Go to www.asegua.com/patient-support or call 1-877-404-3157.
- To learn about potential savings, call 1-855-7-MYPATH or go to www.mysupportpath.com/patients.

