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## Ledipasvir and Sofosbuvir

pronounced as (le dip' as vir) and (soe fos' bue vir)

### IMPORTANT WARNING:

You may already be infected with hepatitis B (a virus that infects the liver and may cause severe liver damage), but not have any symptoms of the disease. In this case, taking the combination of ledipasvir and sofosbuvir may increase the risk that you will develop symptoms and your infection will become more serious or life-threatening. Tell your doctor if you have or ever had a hepatitis B virus infection. Your doctor will order a blood test to see if you have or have ever had hepatitis B infection. Your doctor will also monitor you for signs of hepatitis B infection during and for several months after your treatment. If necessary, your doctor may give you medication to treat this infection before and during your treatment with the combination of ledipasvir and sofosbuvir. If you experience any of the following symptoms during or after your treatment, call your doctor immediately: excessive tiredness, yellowing of the skin or eyes, loss of appetite, nausea, vomiting, pale stools, stomach pain, or dark urine.

Keep all appointments with your doctor and the laboratory. Your doctor may order certain tests before, during, and after your treatment to check your body's response to the combination of ledipasvir and sofosbuvir.

Talk to your doctor about the risk(s) of taking the combination of ledipasvir and sofosbuvir.

### Why is this medication prescribed?

The combination of ledipasvir and sofosbuvir is used alone or in combination with ribavirin (Copegus, Rebetol, Ribasphere, others) to treat certain types of chronic hepatitis C (an ongoing viral infection that damages the liver) in adults and children 3 years of age and older. Sofosbuvir is in a class of antiviral medications called nucleotide polymerase inhibitors. It works by decreasing the amount of hepatitis C virus (HCV) in the body. Ledipasvir is in a class of antiviral medications called HCV NS5A inhibitors. It works by stopping the virus that causes hepatitis C from spreading inside the body.

### How should this medicine be used?

The combination of ledipasvir and sofosbuvir comes as a tablet and pellets to take by mouth. It is usually taken with or without food once daily. Take ledipasvir and sofosbuvir at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take ledipasvir and sofosbuvir exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Ledipasvir and sofosbuvir pellets can be swallowed (without chewing) or they can be taken with food. To prepare a dose of ledipasvir and sofosbuvir pellets with food, sprinkle the entire packet of pellets on one or more spoonfuls of cold or room temperature non-acidic soft food such as pudding, chocolate syrup, mashed potato, or ice cream. Take the entire mixture within 30 minutes of sprinkling the pellets on food. To avoid a bitter aftertaste, do not chew the pellets.

Continue to take ledipasvir and sofosbuvir even if you feel well. The length of your treatment (8 to 24 weeks) depends on your condition, how well you respond to the medication, and whether you experience severe side effects. Do not stop taking ledipasvir and sofosbuvir without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking ledipasvir and sofosbuvir,

- tell your doctor and pharmacist if you are allergic to ledipasvir or sofosbuvir, any other medications, or any of the ingredients in ledipasvir and sofosbuvir tablets or pellets. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: amiodarone (Nexterone, Pacerone); digoxin (Lanoxin); certain medications for cancer; medications for diabetes; certain medications for seizures such as carbamazepine (Carbatrol, Epitol, Equetro, Tegretol), oxcarbazepine (Oxtellar XR, Trileptal), phenobarbital, or phenytoin (Dilantin, Phenytek); medications for heartburn and ulcers; medications for HIV taken together such as efavirenz (Sustiva, in Atripla), emtricitabine (Emtriva, in Atripla) and tenofovir (Viread, in Atripla); elvitegravir (Sustiva, in Atripla), cobicistat (Tybost, in Stribild), emtricitabine (Emtriva, in Stribild), and tenofovir (Viread, in Stribild); tenofovir (Viread), atazanavir (Reyataz) and ritonavir (Norvir); tenofovir (Viread), darunavir (Prezista) and ritonavir (Norvir); tenofovir (Viread), lopinavir (in Kaletra), and ritonavir (Norvir, in Kaletra); or tipranavir (Aptivus) and ritonavir (Norvir); certain medications that suppress the immune system; rifabutin (Mycobutin); rifampin (Rifadin, Rimactane, in Rifamate, in Rifater); rifapentine (Priftin); rosuvastatin (Crestor); simeprevir (Olysio); sofosbuvir (Sovaldi); and warfarin (Coumadin, Jantoven). Your doctor may tell you not to take ledipasvir and sofosbuvir if you are taking one or more of these medications or may monitor you carefully for side effects. Many other medications may also interact with ledipasvir and sofosbuvir, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- if you are taking antacids containing aluminum hydroxide or magnesium hydroxide (Maalox, Mylanta, Tums, others), take them 4 hours before or 4 hours after taking ledipasvir and sofosbuvir.

- tell your doctor if you are taking a medication for indigestion, heartburn, or ulcers (H<sub>2</sub> blockers) such as cimetidine, ranitidine (Zantac), famotidine (Pepcid, in Duexis) or nizatidine. Your doctor may tell you to take them 12 hours before or 12 hours after ledipasvir and sofosbuvir, or at the same time that you take ledipasvir and sofosbuvir.
- tell your doctor what herbal products you are taking, especially St. John's wort. You should not take St. John's wort during your treatment with ledipasvir and sofosbuvir.
- tell your doctor if you have had a liver transplant or if you have human immunodeficiency virus (HIV). Also, tell your doctor if you have or have ever had any type of liver disease other than hepatitis C, kidney disease, or are on dialysis.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking ledipasvir and sofosbuvir, call your doctor. If ledipasvir and sofosbuvir is used in combination with ribavirin, be sure to read information about pregnancy precautions in the ribavirin monograph.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Ledipasvir and sofosbuvir may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- tiredness
- headache
- difficulty falling asleep or staying asleep
- nausea
- diarrhea
- cough
- dizziness
- muscle pain
- irritability

**Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately or get emergency treatment:**

- rash
- blisters

- swelling of the face, arms, or legs
- shortness of breath
- hoarseness
- difficulty swallowing or breathing

Ledipasvir and sofosbuvir may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Do not use if the seal over bottle opening is broken or missing. Store it at room temperature and away from light, excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary

supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Harvoni®

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