

**LISOF  
(Ledipasvir and Sofosbuvir Tablets 90mg/400 mg)**

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**PATIENT INFORMATION LEAFLET**

**PATIENT SUMMARY OF INFORMATION ABOUT [LISOF (Ledipasvir and Sofosbuvir Tablets 90/400 mg)]**

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Read all of this leaflet carefully before you start taking this medicine.**

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

**In this leaflet:**

1. What Ledipasvir and Sofosbuvir Tablet is and what it is used for
2. What you need to know before you take Ledipasvir and Sofosbuvir Tablet
3. How to take Ledipasvir and Sofosbuvir Tablet
4. Possible side effects
5. How to store Ledipasvir and Sofosbuvir Tablet
6. Contents of the pack and other information

**1. WHAT LEDIPASVIR AND SOFOSBUVIR TABLET IS AND WHAT IT IS USED FOR**

Ledipasvir and Sofosbuvir Tablet is a medicine that contains the active substances ledipasvir and sofosbuvir in a single tablet. It is given to treat chronic (long-term) hepatitis C virus infection in adults of 18 years and older.

Hepatitis C is a virus that infects the liver. The active substances in the medicine work together by blocking two different proteins that the virus needs to grow and reproduce itself, allowing the infection to be permanently eliminated from the body.

Ledipasvir and Sofosbuvir Tablet is sometimes taken with another medicine, ribavirin.

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It is very important that you also read the leaflets for the other medicines that you will be taking with Ledipasvir and Sofosbuvir Tablet. If you have any questions about your medicines, please ask your doctor or pharmacist.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LEDIPASVIR AND SOFOSBUVIR TABLET**

Do not take Ledipasvir and Sofosbuvir Tablet

- If you are allergic to ledipasvir, sofosbuvir or any of the other ingredients of this medicine (listed in section 6 of this leaflet).
- If this applies to you, do not take Ledipasvir and Sofosbuvir Tablet and tell your doctor immediately.
- If you are currently taking any of the following medicines:
  - rifampicin and rifabutin (antibiotics used to treat infections, including tuberculosis);
  - St. John's wort (*Hypericum perforatum* – herbal medicine used to treat depression);
  - carbamazepine, phenobarbital and phenytoin (medicines used to treat epilepsy and prevent seizures);
  - rosuvastatin (a medicine used to treat high cholesterol).

Warnings and precautions

Your doctor will know if any of the following conditions apply to you. These will be considered before treatment with Ledipasvir and Sofosbuvir Tablet is started.

- other liver problems apart from hepatitis C, for instance
- if you are awaiting a liver transplant;
- if you have a current or previous infection with the hepatitis B virus, since your doctor may want to monitor you more closely;
- kidney problems, since Ledipasvir and Sofosbuvir Tablet has not been fully tested in patients with severe kidney problems;
- ongoing treatment for HIV infection, since your doctor may want to monitor you more closely.

Talk to your doctor or pharmacist before taking Ledipasvir and Sofosbuvir Tablet if:

- you currently take, or have taken in the last few months, the medicine amiodarone to treat irregular heartbeats (your doctor may consider alternative treatments if you have taken this medicine).

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Tell your doctor immediately if you are taking any medicines for heart problems and during treatment you experience:

- shortness of breath
- light-headedness
- palpitations
- fainting

### Blood tests

Your doctor will test your blood before, during and after your treatment with Ledipasvir and Sofosbuvir Tablet. This is so that:

- Your doctor can decide if you should take Ledipasvir and Sofosbuvir Tablet and for how long;
- Your doctor can confirm that your treatment has worked and you are free of the hepatitis C virus.

### Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age. The use of Ledipasvir and Sofosbuvir Tablet in children and adolescents has not yet been studied.

### Other medicines and Ledipasvir and Sofosbuvir Tablet

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and medicines obtained without a prescription.

Warfarin and other similar medicines called vitamin K antagonists used to thin the blood. Your doctor may need to increase the frequency of your blood tests to check how well your blood can clot.

If you are not sure about taking any other medicines, talk to your doctor or pharmacist.

Some medicines should not be taken with Ledipasvir and Sofosbuvir Tablet.

- Do not take any other medicine that contains sofosbuvir, one of the active substances in Ledipasvir and Sofosbuvir Tablet.
- Do not take any of these medicines with Ledipasvir and Sofosbuvir Tablet
- rifapentine (antibiotic used to treat infections, including tuberculosis);
- oxcarbazepine (a medicine used to treat epilepsy and prevent seizures);
- simeprevir (a medicine used to treat hepatitis C infection);

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- tipranavir (used to treat HIV infection).

Taking Ledipasvir and Sofosbuvir Tablet with any of these may make Ledipasvir and Sofosbuvir Tablet work less well or make any side effects of the medicines worse.

Tell your doctor or pharmacist if you are taking any of the medicines below:

- amiodarone used to treat irregular heartbeats;
- tenofovir disoproxil fumarate or any medicine containing tenofovir disoproxil fumarate, used to treat HIV infection;
- digoxin used to treat heart conditions;
- dabigatran used to thin the blood;
- statins used to treat high cholesterol.

Taking Ledipasvir and Sofosbuvir Tablet with any of these may stop your medicines from working properly, or make any side effects worse. Your doctor may need to give you a different medicine or adjust the dose of medicine you are taking.

- Get advice from a doctor or pharmacist if you take medicines used to treat stomach ulcers, heartburn or acid reflux. This includes: •antacids (such as aluminium/magnesium hydroxide or calcium carbonate). These should be taken at least 4 hours before or 4 hours after Ledipasvir and Sofosbuvir Tablet;

- proton pump inhibitors (such as omeprazole, lansoprazole, rabeprazole, pantoprazole and esomeprazole). These should be taken at the same time as Ledipasvir and Sofosbuvir Tablet. Do not take proton pump inhibitors before Ledipasvir and Sofosbuvir Tablet. Your doctor may give you a different medicine or adjust the dose of the medicine you are taking;

- H<sub>2</sub>-receptor antagonists (such as famotidine, cimetidine, nizatidine or ranitidine). Your doctor may give you a different medicine or adjust the dose of the medicine you are taking.

These medicines can decrease the amount of ledipasvir in your blood. If you are taking one of these medicines your doctor will either give you a different medicine for stomach ulcers, heartburn or acid reflux, or recommend how and when you take that medicine.

Pregnancy and contraception

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The effects of Ledipasvir and Sofosbuvir Tablet during pregnancy are not known. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy must be avoided if Ledipasvir and Sofosbuvir Tablet is taken together with ribavirin. Ribavirin can be very damaging to an unborn baby. Therefore, you and your partner must take special precautions in sexual activity if there is any chance for pregnancy to occur.

- You or your partner must use an effective birth control method during treatment with Ledipasvir and Sofosbuvir Tablet together with ribavirin and for some time afterwards. It is very important that you read the “Pregnancy” section in the ribavirin package leaflet very carefully. Ask your doctor for effective contraceptive method suitable for you.

- If you or your partner become pregnant during Ledipasvir and Sofosbuvir Tablet and ribavirin treatment or in the months that follow, you must contact your doctor immediately.

### **Breast-feeding**

Do not breast-feed during treatment with Ledipasvir and Sofosbuvir Tablet. It is not known whether ledipasvir or sofosbuvir, the two active substances of Ledipasvir and Sofosbuvir Tablet, pass into human breast milk.

### **Driving and using machines**

Do not drive or operate machines if you feel tired after taking your medicine.

### **Ledipasvir and Sofosbuvir Tablet contains lactose**

- Tell your doctor if you are lactose intolerant or intolerant to other sugars. Ledipasvir and Sofosbuvir Tablet contains lactose monohydrate. If you are lactose intolerant, or if you have been told that you have an intolerance to other sugars, talk to your doctor before taking this medicine.

## **3. HOW TO TAKE LEDIPASVIR AND SOFOSBUVIR TABLET**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

### **Recommended dose**

The recommended dose is **one tablet once a day**. Your doctor will tell you for how many weeks you should take Ledipasvir and Sofosbuvir Tablet.

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Swallow the tablet whole with or without food. Do not chew, crush or split the tablet as it has a very bitter taste. Tell your doctor or pharmacist if you have problems swallowing tablets.

**If you are taking an antacid**, take it at least 4 hours before or at least 4 hours after Ledipasvir and Sofosbuvir Tablet.

**If you are taking a proton pump inhibitor**, take it at the same time as Ledipasvir and Sofosbuvir Tablet. Do not take it before Ledipasvir and Sofosbuvir Tablet.

**If you are sick (vomit) after taking Ledipasvir and Sofosbuvir Tablet** it may affect the amount of Ledipasvir and Sofosbuvir Tablet in your blood. This may make Ledipasvir and Sofosbuvir Tablet work less well.

- If you are sick (vomit) **less than 5 hours after** taking Ledipasvir and Sofosbuvir Tablet, take another tablet.
- If you are sick (vomit) **more than 5 hours after** taking Ledipasvir and Sofosbuvir Tablet, you do not need to take another tablet until your next scheduled tablet.

**If you take more Ledipasvir and Sofosbuvir Tablet than you should**

If you accidentally take more than the recommended dose you should contact your doctor or nearest emergency department immediately for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

**If you forget to take Ledipasvir and Sofosbuvir Tablet**

It is important not to miss a dose of this medicine.

If you do miss a dose, work out how long it is since you last took your Ledipasvir and Sofosbuvir Tablet:

- **If you notice within 18 hours** of the time you usually take Ledipasvir and Sofosbuvir Tablet, you must take the tablet as soon as possible. Then take the next dose at your usual time.
- **If it's 18 hours or more** after the time you usually take Ledipasvir and Sofosbuvir Tablet, wait and take the next dose at your usual time. Do not take a double dose (two doses close together).

**Do not stop taking Ledipasvir and Sofosbuvir Tablet**

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Do not stop taking this medicine unless your doctor tells you to. It is very important that you complete the full course of treatment to give the medicine the best chance to treat your hepatitis C virus infection.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine may cause side effects. If you take Ledipasvir and Sofosbuvir Tablet you may get one or more of the side effects below:

**Very common side effects**

*(may affect more than 1 in 10 people)*

- headache
- feeling tired

**Common side effects**

*(may affect up to 1 in 10 people)*

- rash

**Reporting of side effects**

**If you get any side effects, talk to your doctor or pharmacist.**

**5. HOW TO STORE LEDIPASVIR AND SOFOSBUVIR TABLET**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION****What Ledipasvir and Sofosbuvir Tablets 90 mg/400 mg contains**

The active substance is Ledipasvir Premix and Sofosbuvir.

Each film coated tablet contains 90 mg of Ledipasvir and 400 mg of Sofosbuvir.

- The other ingredients are:

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- Lactose Monohydrate (Mod. Spray dry Fast flow), Microcrystalline cellulose (Avicel PH 101), Croscarmellose Sodium (Ac-Di-Sol), Colloidal silicon dioxide (Aerosil 200), Magnesium stearate (Ligamed-MF-2-V), Microcrystalline cellulose (Avicel PH 102), Opadrv II Brown 85F565007 and Purified water.

**What Ledipasvir and Sofosbuvir Tablets 90 mg/400 mg looks like and contents of the pack**

Brown, Capsule shape, bevel edged biconvex, film-coated tablets de bossed with 'H' on one side and 'L 18' on other side.

Ledipasvir and Sofosbuvir Tablets 90 mg/400 mg are available in:

**Container pack:** 28's count

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**Marketing Authorization Holder and Manufacturer**

**Marketing Authorization Holder:**

**Name:** Hetero Labs Limited

**Business Address:** 7-2-A2, Hetero Corporate,  
Industrial Estates,  
Sanath Nagar,  
Hyderabad-500 018  
Telangana.

**Country:** INDIA

**Manufacturer:**

(Company) Name : Hetero Labs Limited (Unit-V)

Address : TSIIC Formulation SEZ, Survey No. 439, 440, 441 & 458, Polepally  
village,  
Jadcherla Mandal, Mahaboob Nagar (Dist) – 509301, Telangana,

Country : India

Telephone : 91-8458-277106/277210

Telefax : 91-8458 277135

E-Mail : [contact@heterodrugs.com](mailto:contact@heterodrugs.com);