

SOFOSLED®

Sofosbuvir/ Ledipasvir
Coated tablet 400/90 mg.

THIS MEDICATION IS SUBJECTED TO AN ADDITIONAL MONITORING WHICH ALLOWS THE RAPID IDENTIFICATION OF NEW SECURITY INFORMATION. YOU CAN HELP BY REPORTING ANY ADVERSE EFFECT THAT YOU OBSERVE.

1-PRESENTATION AND DOSAGE FORM

SOFOSLED® 400/90 mg: Box of 28 coated tablets.

2-COMPOSITION

Each coated tablet contains:

Sofosbuvir.....400 mg
Ledipasvir.....90 mg

- Excipients:

Microcrystalline Cellulose, magnesium stearate, Croscarmellose sodium, hydrophobic colloidal silica, Copovidone, lactose.

Coating: Polyvinyl Alcohol, polyethylene glycol, quinoleine yellow aluminum lacquer, FD&C blue # 2 lacquer, titanium dioxide, talc.

Excipients with known effects:

Lactose..... 165mg/tab

3 - THERAPEUTIC CLASS

Direct acting antiviral

4 - THERAPEUTIC INDICATIONS

SOFOSLED® is a medication containing two active substances Ledipasvir and Sofosbuvir in a single tablet. It is administered to treat chronic infection (long term) caused by hepatitis C virus in adults (18 years and older).

Hepatitis C is a virus that infects the liver. The active substances in this medication 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.

SOFOSLED® is sometimes taken with another medication such as ribavirin.

It is very important that you also read the leaflets for the other medicines that you will be taking with **SOFOSLED®**.

5- DOSAGE AND ADMINISTRATION

Oral use

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

The recommended dose is **one tablet once a day**. Your doctor will tell you for how many weeks you should take **SOFOSLED®**.

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 **SOFOSLED®**.

If you are taking a proton pump inhibitor, take it at the same time as **SOFOSLED®**. Do not take it before **SOFOSLED®**.

If you vomit after taking SOFOSLED®, it may affect the amount of **SOFOSLED®** in your blood.

This may make **SOFOSLED®** work less well.

- If you vomit **less than 5 hours after** taking **SOFOSLED®**, take another tablet.
- If you vomit **more than 5 hours after** taking **SOFOSLED®**, you do not need to take another tablet until your next scheduled tablet.

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.

STRICT RESPECT TO THE DOSAGE PRESCRIBED BY YOUR DOCTOR. IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK FOR THE DOCTOR OR THE PHARMACIST OPINION.

6- CONTRAINDICATIONS

Do not take **SOFOSLED®**:

- If you are allergic to Ledipasvir, sofosbuvir or any of the other ingredients of this medicine
- If you are currently taking any of the following medicines:
 - **St. John's wort** (*Hypericum perforatum* – herbal medicine used to treat depression);
 - **Rosuvastatin** (a medicine used to treat high cholesterol).

IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK FOR THE DOCTOR OR THE PHARMACIST OPINION.

7- WARNINGS AND PRECAUTIONS:

Your doctor will know if any of the following conditions apply to you. These will be considered before treatment with **SOFOSLED®**.

- **Other liver problems** apart from hepatitis C, for instance
 - **if you are awaiting a liver transplant;**
 - **if you have hepatitis B**, since your doctor may want to monitor you more closely;

- **Kidney problems**, since **SOFOSLED®** 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.

Your doctor will test your blood before, during and after your treatment with **SOFOSLED®**.

The co-administration of **SOFOSLED®** with amiodarone should be avoided because of existence of risk of arrhythmia. If the co-administration with **SOFOSLED®** is necessary, patients should be closely monitored.

Tell your doctor immediately if you are taking any medicines for heart problems and during treatment you experience shortness of breath, light-headedness, palpitations and fainting.

Do not give this medicine to children and adolescents under 18 years of age. The use of **SOFOSLED®** in children and adolescents has not yet been studied.

The use of this medication is not recommended in patients with galactose intolerance, lactase deficiency, or glucose-galactose malabsorption (rare metabolic disease).

IN CASE OF DOUBT, DO NOT HESITATE TO ASK FOR YOUR DOCTOR OR PHARMACIST OPINION.

8-DRUG INTERACTIONS

TO AVOID POSSIBLE DRUG INTERACTIONS, YOU SHOULD SYSTEMATICALLY REPORT ANY OTHER TREATMENT TO YOUR DOCTOR OR YOUR PHARMACIST. This includes herbal medicines and medicines obtained without a prescription.

Do not take any other medicine that contains sofosbuvir, one of the active substances in SOFOSLED®.

Do not take any of these medicines with SOFOSLED®:

- **Rifampicin, rifapentine, rifabutin** (antibiotics used to treat tuberculosis);
- **Carbamazepine, phenytoin, phenobarbital, oxcarbazepine** (medicines used to treat epilepsy and prevent seizures);
- **Statins:** medications used to treat high cholesterol such as **pravastatin**;
- **Simeprevir** (a medicine used to treat hepatitis C infection);
- **Tipranavir** (used to treat HIV infection).

Taking **SOFOSLED®** with any of these medications may make it work less well or make any side effects of the medicines worse.

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 aluminum/magnesium hydroxide or calcium carbonate). These should be taken at least 4 hours before or 4 hours after **SOFOSLED®**;
- Proton pump inhibitors (such as omeprazole, lansoprazole, rabeprazole, pantoprazole and esomeprazole). These should be taken at the same time as **SOFOSLED®**. Do not take proton pump inhibitors before **SOFOSLED®**. Your doctor may give you a different medicine or adjust the dose of the medicine you are taking;
- H₂-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.

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;

Taking **SOFOSLED®** 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.

IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK FOR THE DOCTOR OR THE PHARMACIST OPINION.

9- PREGNANCY AND BREASTFEEDING

Pregnancy

The effects of **SOFOSLED®** 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 **SOFOSLED®** 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 **SOFOSLED®** together with ribavirin and for some time afterwards. It is very

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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 **SOFOSLED®** and ribavirin treatment or in the months that follow, you must contact your doctor immediately.

Breast-feeding

Do not breast-feed during treatment SOFOSLED®. It is not known whether ledipasvir or sofosbuvir, the two active substances of **SOFOSLED®**, pass into human breast milk.

GENERALLY, YOU SHOULD ASK THE OPINION OF YOUR DOCTOR OR PHARMACIST DURING PREGNANCY AND BREASTFEEDING BEFORE TAKING ANY MEDICATION.

10- DRIVING AND USING MACHINES

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

11- POSSIBLE ADVERSE EFFECTS

Like all medications, **SOFOSLED®** may cause side effects. If you take **SOFOSLED®** you may get one or more of the side effects below:

Very common side effects

- Fever, chills, flu-like symptoms
- Diarrhea, nausea, vomiting
- Trouble sleeping (insomnia)
- Feeling tired and irritable
- Headache
- Rash, itchy skin
- Loss of appetite
- Feeling dizzy
- Muscle aches and pains, pain in the joints
- Shortness of breath, cough

Blood tests may also show:

- low red blood cell count (anemia); the signs may include feeling tired, headaches, shortness of breath when exercising
- low white blood cell count (neutropenia); the signs may include getting more infections than usual, including fevers and chills, or sore throat or mouth ulcers
- low blood platelet count
- changes in your liver (as shown by increased amounts of a substance called bilirubin in the blood)

Common side effects

- changes in your mood, feeling depressed, feeling anxious and feeling agitated
- blurred vision
- severe headaches (migraine), memory loss, loss of concentration
- weight loss
- shortness of breath when exercising
- stomach discomfort, constipation, dry mouth, indigestion, acid reflux
- hair loss and thinning hair
- dry skin
- back pain, muscle spasms
- chest pain, feeling weak
- getting a cold (nasopharyngitis)

If any of the side effects get serious tell your doctor.

REPORT TO YOUR DOCTOR OR YOUR PHARMACIST ANY UNDESIRABLE ADVERSE EFFECT THAT IS NOT MENTIONED IN THIS LEAFLET.

12- OVERDOSE:

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

13-FORGETTING ONE OR MANY DOSES

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 **SOFOSLED®**:

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

14- STORAGE:

Store in the original external packaging at temperature not more than 25° C away from light and humidity.

Keep out of the sight and reach of children.

Do not use after the expiry date printed on the box.

List I
D E n°:

Registration decision holder:

BEKER Laboratories
Cité Aissat Idir, Dar El Beida16100, Alger

Manufacturer/Packager:

BEKER Laboratories, Algeria
ZA, extension Dar El Beida, cité Fatma N'soumer, N°18 Dar El Beida 16100, Alger



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