

SOFOS[®]

Sofosbuvir

Coated tablet 400 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

SOFOS[®] 400 mg: Box of 28 coated tablets.

2-COMPOSITION

Each coated tablet contains:

Sofosbuvir.....400 mg

- Excipients:

Cellulose microcrystalline, magnesium stearate, mannitol, croscarmellose sodium, silica colloidal anhydrous.

Coating: hypromellose, red ferric oxide, yellow ferric oxide, titanium dioxide, maltodextrine, talc, polydextrose, medium chain triglycerides ponceau 4R red lacquer, FD& C yellow #6 (yellow orange-S) aluminum lacquer

Excipients with known effects :

Each coated tablet contains:

Yellow orange-S (E110).....0.031mg

Red ponceau (E124).....0.008mg

3 - THERAPEUTIC CLASS

Direct acting antiviral

4 - THERAPEUTIC INDICATIONS

SOFOS[®] is a medication used to treat infection by hepatitis C virus in adults (adults of 18 years and older.).

Hepatitis C is an infection of the liver due to a virus. This medicine works by lowering the amount of hepatitis C virus in your body and removing the virus from your blood over a period of time.

SOFOS[®] is always taken with other medicines. It will not work on its own. It is commonly taken with either:

- Ribavirin , or
- Peginterferon alfa and ribavirin

It is very important that you also read the leaflets for the other medicines that you will be taking with **SOFOS[®]**. If you have any questions about your medicines, please ask your doctor or pharmacist.

5-DOSAGE AND ADMINISTRATION

Oral use

The recommended dose is **one tablet once a day** with food. Your doctor will tell you for how long you should take **SOFOS[®]**

Swallow the tablet whole. 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.

SOFOS[®] should always be taken in combination with other medicinal products for use against hepatitis C.

If you vomit **less than 2 hours** after taking **SOFOS[®]**, take another tablet. If you vomit **more than 2 hours** after taking it you do not need to take another tablet until your next regularly scheduled tablet.

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 **SOFOS[®]**:

- If you are allergic to sofosbuvir or any of the other ingredients of this medication.

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

7- WARNINGS AND PRECAUTIONS:

SOFOS[®] is always taken with other medicines. Talk to your doctor or pharmacist before taking this medicine if you:

- Have liver problems other than hepatitis C, e.g. if you are awaiting a liver transplantation;
- Have hepatitis B, since your doctor may want to monitor you more closely;
- Have kidney problems. Talk to your doctor or pharmacist if you have severe kidney problems or if you are on kidney dialysis as the effects of **SOFOS[®]** on patients with severe kidney problems have not been fully tested.

Your doctor will test your blood before, during and after your treatment with

SOFOS[®]. This is so your doctor can:

- Decide what other medicines you should take with **SOFOS[®]** and for how long;
- Confirm that your treatment has worked and you are free of the hepatitis C virus.

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

Children and adolescents

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

This medication contains azo dyes (E110 & E124) and may trigger allergic reaction.

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.

In particular, do not take **SOFOS[®]** if you are taking any of the following medicines:

- Rifampicin (antibiotic used to treat infections, including tuberculosis);
- St. John's wort (*Hypericum perforatum* – herbal medicine used to treat depression);
- Carbamazepine and phenytoin (medicines used to treat epilepsy and prevent seizures).

This is because they may make **SOFOS[®]** work less well.

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

9- PREGNANCY AND BREASTFEEDING

Pregnancy

- **SOFOS[®]** is commonly used together with ribavirin. Ribavirin can damage your unborn baby. It is therefore very important that you (or your partner) **do not become pregnant** during this therapy.

- You or your partner must use an effective birth control method **during treatment and 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 **SOFOS[®]** treatment or in the months that follow, you must **contact your doctor immediately**.

Breastfeeding

You should not breast-feed during treatment with SOFOS[®]. It is not known whether sofosbuvir, the active substance of **SOFOS[®]**, passes 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

When taking **SOFOS[®]** together with other medicines for the treatment of hepatitis C infection, patients have reported tiredness, dizziness, blurred vision and reduced attention. If you have any of these side effects, do not drive or use any tools or machines.

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Sofosbuvir

Coated tablet 400 mg.

11- POSSIBLE ADVERSE EFFECTS

Like all medications, **SOFOS[®]** taken alone or with ribavirine or peginterferon alfa and ribavirine, may have undesirable effects.

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 of **SOFOS[®]** 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:

- **and you notice within 18 hours** of the time you usually take **SOFOS[®]**, you must take the tablet as soon as possible. Then take the next dose at your usual time.
- **and you notice 18 hours or more** after the time you usually take **SOFOS[®]**, 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 humidity.

Keep out of the sight and reach of children..

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

List I

Registration decision 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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