

SOFOVIR SOFOSBUVIR TABLETS 400MG

Sofosbuvir (400 mg)

What is in this leaflet

1. What SOFOVIR is used for
2. How SOFOVIR works
3. Before you use SOFOVIR
4. How to use SOFOVIR
5. While you are using it
6. Side effects
7. Storage and Disposal of SOFOVIR
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What SOFOVIR is used for

SOFOVIR is used in combination with other medicinal products for the treatment of chronic hepatitis C in adults.

How SOFOVIR works

Hepatitis C is a virus that infects the liver. 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. This product 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 Sofosbuvir. If you have any questions about your medicines, please ask your doctor or pharmacist.

Before you use SOFOVIR

- When you must not use it

Do not take SOFOVIR if you:

- You are allergic (hypersensitive) to sofosbuvir or to any one of the ingredients of this medicine.

- Before you start to use it

Tell your doctor if you have any of the following:

- a) Have liver problems other than hepatitis C, e.g. if you are awaiting a liver transplantation.
- b) Have a current or previous infection with the hepatitis B virus, since your doctor may want to monitor you more closely.
- c) Have kidney problems
- d) 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) Tell your doctor immediately if you are taking any medicines for heart problems and during treatment you experience:

- Shortness of breath or worsening of any shortness of breath you already have
- Light-headedness
- Palpitations
- Fainting
- e) Blood tests

Your doctor will test your blood before, during and after your treatment with SOFOVIR. This is so your doctor can:

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

f) Children and adolescents

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

g) Other medicines and SOFOVIR

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.
- Tell your doctor if you take any of the following medicines:

- Amiodarone, used to treat irregular heartbeats

- Taking other medicines

SOFOVIR may influence the effectiveness of other medicines, so tell your doctor if you are taking:

- a) Rifampicin and rifabutin (antibiotics used to treat infections, including tuberculosis)
- b) St. John's wort (Hypericum perforatum – herbal medicine used to treat depression)
- c) Carbamazepine, phenobarbital and phenytoin (medicines used to treat epilepsy and prevent seizures).
- d) Oxcarbazepine (a medicine used to treat epilepsy and prevent seizures).
- e) Modafinil (a medicine to treat people

with narcolepsy to help them stay awake).

- f) Amiodarone, used to treat irregular heartbeats.

How to use SOFOVIR

Always take SOFOVIR tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

SOFOVIR tablets should be administered orally. Swallow the tablet as a whole. Do not chew or crush the tablet due to the bitter taste of the active substance. The tablet should be taken with food.

- How much to use

The recommended dose is one 400 mg tablet, taken orally, once daily with food.

– SOFOVIR should be used in combination with other medicinal products.

– If the other medicinal products used in combination with SOFOVIR are permanently discontinued, SOFOVIR should also be discontinued

SOFOVIR treatment should be initiated and monitored by a physician experienced in the management of patients with Hepatitis.

- When to use it

Take the medicine as instructed by your doctor. Preferably take at the same time each day.

- How long to use it

Your doctor will tell you for how long you should take SOFOVIR.

- If you forget to use it

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 SOFOVIR, 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 SOFOVIR, wait and take the next dose at your usual time. Do not take a double dose (two doses close together).

- If you use too much (overdose)

If you accidentally take more than the recommended dose you should contact your doctor or nearest emergency department

SOFOVIR SOFOSBUVIR TABLETS 400MG

Sofosbuvir (400 mg)

immediately for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

While you are using it

- Things you must do

Always take SOFOVIR exactly as your doctor has told you.

SOFOVIR should always be taken in combination with other medicinal products for use against hepatitis C.

If you are sick (vomit) less than 2 hours after taking SOFOVIR, 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.

- Things you must not do

Do not stop taking the tablets without first talking to your doctor or pharmacist.

Do not take more than the recommended dose.

- Things to be careful of

Driving and using machines

When taking SOFOVIR 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.

Pregnancy and breast feeding

Pregnancy must be avoided due to the use of SOFOVIR together with ribavirin. Ribavirin can be very damaging to an unborn baby. Hence, women of childbearing potential or their male partners must use an effective form of contraception during the treatment and for a period of time after the treatment.

If you or your partner become pregnant during SOFOVIR treatment or in the months that follow, you must contact your doctor immediately.

Breast-feeding

You should not breast-feed during treatment with SOFOVIR. It is not known

whether sofosbuvir, the active substance of SOFOVIR, passes into human breast milk.

Side effects

Like all medicines, SOFOVIR tablets can cause side effects although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

When you take SOFOVIR in combination with another medicine to treat hepatitis C virus infection (including daclatasvir, simeprevir and ledipasvir) and amiodarone (a medicine used for heart problems), you may get one or more of the side effects below:

- slow or irregular heartbeat or heart rhythm problems
 - shortness of breath or worsening of any shortness of breath you already have
- Tell your doctor or your pharmacist if you notice any of the above side effects during therapy.

When you take SOFOVIR with ribavirin or both peginterferon alfa and ribavirin, you may get one or more of the side effects below:

Very common side effects

- fever, chills, flu like symptoms
- diarrhoea, feeling sick (nausea), being sick (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 (anaemia); 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)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03- 78835490, or visiting the website npra.gov.my (Consumer Reporting □ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

Storage and Disposal of Pantaz tablets

- Storage

Store below 30°C and protect from moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

SOFOVIR Sofosbuvir Tablets 400mg are Orange oval, bevel biconvex, film coated tablets debossed with 'H' on one side and 'S14' on the other side..

- Ingredients

- Active ingredient: Sofosbuvir 400 mg

- Inactive ingredients

Mannitol, Microcrystalline Cellulose, Croscarmellose Sodium, Colloidal Silicon Dioxide, Magnesium stearate, Opadry II

SOFOVIR SOFOSBUVIR TABLETS 400MG

Sofosbuvir (400 mg)

Orange.

- MAL number: xxxxxx

Manufacturer

HETERO LABS LIMITED
UNIT-V, Sy. No. 439, 440, 441 & 458,
TSIIC Formulation SEZ,
Polepally Village, Jadcherla Mandal,
Mahaboobnagar Dist., Telangana, India.

Product Registration Holder

SYNERRV SDN BHD,
S0-29-2, Menara 1, KL Eco City,
Jalan Bangsar, Kg Haji Abdullah Hukum,
59200 Kuala Lumpur

Date of revision

02/07/2019

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