

Sovaldi™

400 mg film-coated tablets
sofosbuvir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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

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

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

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Sovaldi is and what it is used for

Sovaldi contains the active substance sofosbuvir which is given to treat hepatitis C virus infection in adults of 18 years and older.

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.

Sovaldi 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 Sovaldi. If you have any questions about your medicines, please ask your doctor or pharmacist.

2. What you need to know before you take Sovaldi

Do not take Sovaldi

- If you are allergic to sofosbuvir or any of the other ingredients of this medicine (listed in section 6 of this leaflet).

➔ **If this applies to you, tell your doctor immediately.**

Warnings and precautions

Sovaldi is always taken with other medicines (see section 1 above). 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 Sovaldi on patients with severe kidney problems have not been fully tested.

Blood tests

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

- Decide what other medicines you should take with Sovaldi and for how long;
- 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 Sovaldi in children and adolescents has not yet been studied.

Other medicines and Sovaldi

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.

In particular, do not take Sovaldi if you are taking any of the following medicines:

- Amiodarone (a medicine used to treat heart rhythm disorders);
- 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 Sovaldi work less well.

If you are not sure, talk to your doctor or pharmacist.

Pregnancy and contraception

Pregnancy must be avoided due to the use of Sovaldi 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.

- Sovaldi 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 Sovaldi treatment or in the months that follow, you must **contact your doctor immediately**.

Breast-feeding

You should not breast-feed during treatment with Sovaldi. It is not known whether sofosbuvir, the active substance of Sovaldi, passes into human breast milk.

Driving and using machines

When taking Sovaldi 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.

3. How to take Sovaldi

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** with food. Your doctor will tell you for how long you should take Sovaldi.

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.

Sovaldi 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 Sovaldi, 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.

If you take more Sovaldi 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 Sovaldi

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

Do not stop taking Sovaldi

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 medicines 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 can cause side effects, although not everybody gets them.

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

Very common side effects

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

- 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

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

- 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.**

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sovaldi

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.

Store below 30°C.

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 to protect the environment.

6. Contents of the pack and other information

What Sovaldi contains

▪ **The active substance is** sofosbuvir. Each film-coated tablet contains 400 mg of sofosbuvir.

▪ **The other ingredients are**

Tablet core:

Mannitol, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.

Film-coating:

Polyvinyl alcohol, titanium dioxide, macrogol 3350, talc, yellow iron oxide.

What Sovaldi looks like and contents of the pack

The film-coated tablets are yellow, capsule-shaped tablets, debossed on one side with "GSI" and "7977" on the other side.

Each bottle contains a silica gel desiccant (drying agent) that must be kept in the bottle to help protect your tablets. The silica gel desiccant is contained in a separate sachet or canister and should not be swallowed.

The following pack size is available: outer carton containing 1 bottle of 28 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

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To report any side effect(s):

Please contact the relevant competent authority

THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions for the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach of children.

Council of Arab Health Ministers and
Union of Arab Pharmacists

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