

SOVALDI[®] Tablets

400 mg Sofosbuvir

Consumer Medicine Information

What is in this leaflet

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

This leaflet answers some common questions about SOVALDI tablets.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist about your medical condition or treatment.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist or doctor and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SOVALDI against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

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

What is SOVALDI used for

SOVALDI is given with other medicines to treat hepatitis C virus infection (also called HCV infection)

in adults and pediatric patients 12 years of age and older.

Hepatitis C is a virus that infects the liver.

How SOVALDI works

SOVALDI contains the active ingredient sofosbuvir.

SOVALDI works together with other medicines by lowering the amount of hepatitis C virus in your body and may lead to a cure of your HCV infection over at least 12 weeks.

Cure means the HCV virus is cleared from your blood (remains at an undetectable level) when measured 3 months after finishing all treatment.

SOVALDI does not protect against re-infection with the HCV virus if cure has been achieved.

SOVALDI must always be taken together with other medicines as it will not work on its own.

Ask your doctor if you have any questions about why SOVALDI has been prescribed for you.

Use in children

SOVALDI is for adults and pediatric patients 12 years of age and older. SOVALDI has not been studied in children under the age of 12.

Before you take SOVALDI

When you must not take it

Together with your doctor, you need to decide whether SOVALDI is right for you.

Do not take SOVALDI if you are allergic to:

- sofosbuvir or

- any of the other ingredients of SOVALDI. The ingredients of SOVALDI are listed in the product description section of this leaflet.

Some people are allergic to medicines. If you have any of the following symptoms soon after taking your medicine, **DO NOT TAKE ANY MORE SOVALDI** and tell your doctor **IMMEDIATELY** or go to the accident and emergency department at your nearest hospital:

- Skin troubles such as lumpy skin rash or “hives”
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Wheezing, chest pain or tightness
- Fainting

These are very serious effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation. Hypersensitivity reactions are very rare.

Ask your doctor or pharmacist if you don't understand anything in this list.

If you are pregnant think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take SOVALDI after the expiry or “use by” date (EXP) printed on the bottle.

If you take it after the expiry date has passed, it may not work as well.

Do not take SOVALDI if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to foods, dyes, preservatives or any other medicines.

Tell your doctor if you have, or have had, any of the following medical conditions:

- Have liver problems, other than hepatitis C
- Have a current or previous infection with the hepatitis B virus, since your doctor may want to monitor you more closely
- Have HIV infection
- Have severe kidney problems or if you are on haemodialysis as the effects of SOVALDI on patients with severe kidney problems have not been fully tested.
- Have any other medical condition

Tell your doctor if you:

- Are pregnant or planning to become pregnant. SOVALDI is commonly used together with ribavirin or with peginterferon alfa and ribavirin. Ribavirin can damage your unborn baby. It is therefore absolutely essential that you (and your partner) take all precautions not to get pregnant during this therapy. You and your partner must use an effective birth control method during ribavirin treatment and during the 6 months after ribavirin treatment. It is very important that you read the “Pregnancy” section in the ribavirin product information very carefully.
- Are breastfeeding or plan to breast-feed. It is not known if SOVALDI can pass into your breast milk and if it can harm your baby. Talk with your doctor about the best way to feed your baby.

If you have not told your doctor or pharmacist about any of the above,

tell them before you start taking SOVALDI.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and SOVALDI may interfere with each other. Tell your doctor if you are taking any of the following medicines:

- modafinil
- amiodarone used to treat heart conditions
- Warfarin or other similar medicines called vitamin K antagonists used to thin the blood.
- carbamazepine, phenytoin (medicines used to treat epilepsy and prevent seizures).
- rifampicin, rifapentine, rifabutin (antibiotics used to treat infections, including tuberculosis);
- St. John’s Wort (*Hypericum perforatum* – herbal medicine used to treat depression)
- tipranavir used to treat HIV infection

These medicines may be affected by SOVALDI or may affect how well it works. You may need different amounts of the medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you. It is very important to let your doctor or pharmacist know what medications, herbal supplements, or vitamins you are taking.

Know the medicines you take. Keep a list of medicines and show it to your doctor and pharmacist when you get a new medicine. Your doctor and your pharmacist can tell you if you can take these medicines with SOVALDI. Do not start any new medicines while you are taking

SOVALDI without first talking with your doctor or pharmacist.

Your doctor and pharmacist may have more information on medicines to be careful with or to avoid while taking SOVALDI.

How to take SOVALDI

Follow all directions given to you by your doctor or pharmacist carefully.

How much to take

Take the exact amount of SOVALDI your doctor has prescribed for you. Never change the dose on your own. Do not stop this medicine unless your doctor tells you to stop.

How much to take

The dose is one SOVALDI tablet orally, once daily.

How to take it

SOVALDI tablets can be taken with or without food.

When to take it

Take SOVALDI at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you forget to take it

Do not miss a dose of SOVALDI. If you forget to take SOVALDI, take your missed dose right away unless it is almost time for your next dose.

Do not take a double dose to make up for a forgotten dose. Continue with your regular dosing schedule.

Do not stop taking SOVALDI 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 cure your hepatitis C virus infection.

Do not change your dose or stop taking SOVALDI without first talking to your doctor, unless you suspect a serious allergic reaction (see *When you must not take it* above).

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre: 131126 (Australia) and 0800 764 766 (New Zealand) or go to the Accident and Emergency department at your nearest hospital if you think you or anyone else may have taken too many SOVALDI tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking SOVALDI

Things you must do

Tell all doctors and pharmacists who are treating you that you are taking SOVALDI.

Tell your doctor as soon as possible if there is any worsening of your condition.

Things you must not do

Do not give SOVALDI to anyone else, even if they have the same condition as you.

Do not stop taking SOVALDI or change the dose without checking with your doctor.

It is important not to suddenly stop taking your SOVALDI tablets, unless advised to do so by your doctor, since your condition may worsen.

Do not breastfeed. See “*Before you take SOVALDI*”.

Things to be careful of

Be careful driving or operating machinery until you know how SOVALDI affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SOVALDI.

SOVALDI helps most people with Hepatitis C infection, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Do not be alarmed by these lists of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- feeling tired and irritable
- headache
- diarrhoea, feeling sick (nausea), being sick (vomiting)
- trouble sleeping (insomnia)
- rash, itchy skin
- loss of appetite
- feeling dizzy
- muscle aches and pains, pain in the joints

- fever, chills, flu-like symptoms
- shortness of breath, cough

Tell with your doctor as soon as possible if you have any problems while taking SOVALDI, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Tell your doctor immediately if you or your family notice any of the following side effects:

- signs of allergy such as rash or hives on the skin; swelling of the face, lips, tongue or other parts of the body; wheezing or difficulty breathing

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking SOVALDI

Storage

Keep SOVALDI tablets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

Keep SOVALDI tablets in a cool, dry place where it stays below 30 °C.

Do not store SOVALDI or any other medicine in a bathroom or near a sink. Do not leave SOVALDI in the car or on a window sill – heat and dampness can destroy some medicines.

Keep your SOVALDI tablets in the bottle with the cap tightly closed until you take them. If you take SOVALDI tablets out of their pack they may not keep well.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your

pharmacist what to do with any
medicine that is left over.

Product description

What it looks like

SOVALDI tablets are capsuled-shaped and yellow in colour. Each tablet has “GSI” on one side and “7977” on the other side of the tablet.

SOVALDI tablets are supplied in bottles containing 28 tablets.

Ingredients

Active Ingredients: sofosbuvir

Inactive Ingredients: mannitol, microcrystalline cellulose, croscarmellose sodium, silicon dioxide and magnesium stearate.

Film coating: polyvinyl alcohol, titanium dioxide, macrogol, talc purified, and iron oxide yellow.

Sponsor

Australia:

Gilead Sciences Pty Ltd
Level 6, 417 St Kilda Road
Melbourne, Victoria 3004

New Zealand:

Gilead Sciences (NZ)
c/- Grant Thornton New Zealand
Limited, L4, 152 Fanshawe Street
Auckland 1010

This leaflet was prepared in March
2018

AUST R 211019

SOVALDI, 7977 and GSI are trademarks of Gilead Sciences, Inc. or one of its related companies. Other brands listed are trademarks of their respective owners and are not trademarks of Gilead Sciences, Inc.