

## Package leaflet: Information for the user

### 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**

1. What Sovaldi is and what it is used for
2. What you need to know before you take Sovaldi
3. How to take Sovaldi
4. Possible side effects
5. How to store Sovaldi
6. Contents of the pack and other information

**If Sovaldi has been prescribed for your child, please note that all the information in this leaflet is applicable to your child (in this case please read “your child” instead of “you”).**

#### **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 and children 3 years of age 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 to treat hepatitis C. It will not work on its own. It is commonly taken with either:

- Ribavirin (children and adult patients), or
- Peginterferon alfa and ribavirin (adult patients)

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 you are currently taking any of the following medicines:**
  - **Rifampicin** (antibiotic used to treat infections, including tuberculosis);
  - **St. John’s wort** (herbal medicine used to treat depression);
  - **Carbamazepine, phenobarbital and phenytoin** (medicines used to treat epilepsy and prevent seizures).

→If any of these conditions apply to you, tell your doctor immediately.

### Warnings and precautions

Sovaldi is always taken with other medicines to treat hepatitis C (see section 1 above). Talk to your doctor or pharmacist before taking this medicine if you:

- currently take, or have taken in the last few months, the medicine amiodarone to treat irregular heartbeats, as it may result in a life-threatening slowing of your heart beat. Your doctor may consider different treatments if you have taken this medicine. If treatment with Sovaldi is needed, you may require additional heart monitoring;
- have liver problems other than hepatitis C, e.g. if you are awaiting a liver transplantation;
- have a current or previous infection with the hepatitis B virus, since your doctor may want to monitor you more closely;
- have diabetes. You may need closer monitoring of your blood glucose levels and/or adjustment of your diabetes medication after starting Sovaldi. Some diabetic patients have experienced low sugar levels in the blood (hypoglycaemia) after starting treatment with medicines like Sovaldi.

**Tell your doctor immediately** if you currently take, or have taken in the last months, any medicines for heart problems and during treatment you experience:

- slow or irregular heartbeat, or heart rhythm problems;
- shortness of breath or worsening of existing shortness of breath;
- chest-pain;
- light-headedness;
- palpitations
- near fainting or fainting

### 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 under 3 years of age. The use of Sovaldi in children under 3 years of age 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.

Warfarin and other similar medicines called vitamin K antagonists are 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.

Your liver function may change with treatment of hepatitis C and therefore may affect other medications (e.g. medicines used to suppress your immune system, etc.). Your doctor may need to closely monitor these other medicines you are taking and make adjustments after starting Sovaldi.

Talk to your doctor about taking Sovaldi if you are taking any of the following medicines:

- Oxcarbazepine (a medicine used to treat epilepsy and prevent seizures);
- Modafinil (a medicine to treat people with narcolepsy to help them stay awake).
- Rifapentine (a medicine used to treat infections, including tuberculosis);

This is because they may make Sovaldi work less well.

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

- amiodarone, used to treat irregular heartbeats.

If you are not sure of what medicines can be taken with Sovaldi, talk to your doctor or pharmacist.

### **Pregnancy and contraception**

Pregnancy must be avoided due to the use of Sovaldi together with ribavirin. It is very important that you read the "Pregnancy" section in the ribavirin package leaflet very carefully. Ribavirin can be very damaging to an unborn baby. Therefore, special precautions in sexual activity must be taken 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 an 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 feel tired, dizzy, have blurred vision or reduced attention after taking Sovaldi you should not take part in activities such as driving, riding a bike or operating machines.

### **Sovaldi contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **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**

**Sovaldi is to be taken as advised by your doctor.** The recommended dose of Sovaldi **in adults** is **one tablet (400 mg) once a day** with food. Your doctor will tell you for how long you should take Sovaldi.

The recommended dose of Sovaldi **in children aged 3 years and above is based on weight. Take Sovaldi with food, as advised by your doctor.**

Swallow the tablet(s) 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 as advised by your doctor.

If you are sick (vomit) **less than 2 hours** after taking Sovaldi, take another dose. If you vomit **more than 2 hours** after taking Sovaldi you do not need to take another dose until your next regularly scheduled dose.

### **Kidney problems**

Tell your doctor if you have kidney problems or if you are on kidney dialysis.

### **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 dose 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 in combination with 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 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, decreased 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)

Other effects that may be seen during treatment with sofosbuvir:

The frequency of the following side effects is not known (frequency cannot be estimated from the available data).

- a wide-spread severe rash with peeling skin which may be accompanied by fever, flu-like symptoms, blisters in the mouth, eyes, and/or genitals (Stevens-Johnson syndrome).

**→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

*Yellow Card Scheme*

*Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store*

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.

This medicine does not require any special storage conditions.

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 or 200 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, iron oxide yellow.

**What Sovaldi looks like and contents of the pack**

Sovaldi 400 mg film-coated tablets are yellow, capsule-shaped tablets, debossed on one side with “GSI” and “7977” on the other side. The tablet is approximately 20 mm long and 9 mm wide.

Sovaldi 200 mg film-coated tablets are yellow, oval-shaped, film-coated tablets, debossed with “GSI” on one side and “200” on the other side. The tablet is approximately 15 mm long and 8 mm wide.

Each bottle of Sovaldi 400 mg film-coated tablets 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 sizes are available:

- outer cartons containing 1 bottle of 28 film-coated tablets for the 400 mg and 200 mg film-coated tablets
- and 84 (3 bottles of 28) film-coated tablets for the 400 mg film coated tablets only. Not all pack sizes may be marketed in your country.

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