

SOVODAK®

(Daclatasvir 60 mg / Sofosbuvir 400 mg)

Packaging leaflet: Information for the patient SOVODAK®

(Daclatasvir 60mg / Sofosbuvir 400 mg film-coated tablets)

Read this leaflet carefully before you start taking this medicine; it contains important information.

- 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 observe 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 SOVODAK® is and what it is used for
2. What you need to know before you take SOVODAK®
3. How to take SOVODAK®
4. Possible side effects
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1. What SOVODAK® is and what it is used for

SOVODAK® contains the active ingredients Daclatasvir 60mg and Sofosbuvir 400mg (yellow tablet). It is used to treat adults with hepatitis C, an infectious disease that affects the liver, caused by the hepatitis C virus.

This medicine works by stopping the hepatitis C virus from multiplying and infecting new cells. This lowers the amount of hepatitis C virus in your body and removes the virus from your blood over a period of time.

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

2. What you need to know before you take SOVODAK®

Do not take SOVODAK®

- If you are taking **amiodarone** (a drug used to treat heartbeat irregularities).
- If you are allergic to Sofosbuvir, Daclatasvir or any of the other ingredients of this medicine (listed in section 6 of this leaflet)
- If you are taking medicines containing St. John's wort (*Hypericum perforatum*, a herbal preparation).
- If you are pregnant or breast feeding

Warnings and precautions

Talk to your doctor or pharmacist before taking SOVODAK®.

Tell your doctor if any of the following applies:

- You have an infection with the human immunodeficiency virus (HIV) or a hepatitis B infection,
- You have had, or are waiting to have a liver or another organ transplant,
- Your liver is damaged and not functioning properly (decompensated liver disease),
- You have kidney problems. Talk to your doctor or pharmacist

if you have severe kidney problems or if you are on hemodialysis as the effects of SOVODAK® 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 SOVODAK®.

This is so your doctor can:

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

Children and adolescents

SOVODAK® is not recommended for patients below 18 years of age. SOVODAK® has not yet been studied in children and adolescents.

Other medicines and SOVODAK®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because SOVODAK® may affect the way some medicines work. In addition some medicines may affect the way SOVODAK® works. Your doctor may need to adjust the dose of SOVODAK® or your other medicines. You may not be able to take SOVODAK® with certain medicines.

DO NOT take SOVODAK® if you are taking **amiodarone** (used to treat cardiac arrhythmias, heart beat irregularities) even if you have stopped less than 6 months ago.

Tell your doctor if you take any of the following medicines. Your doctor might want to change the dose of your medicine or implement additional safety measures:

- Phenytoin, carbamazepine, oxcarbazepine or phenobarbital (used to treat epileptic seizures)
- Rifampicin, rifabutin or rifapentine, (antibiotics used to treat tuberculosis)
- Dexamethasone, (a steroid used to treat allergic and inflammatory diseases),
- medicines containing St. John's wort (*Hypericum perforatum*, a herbal preparation),
- Tipranavir, atazanavir, saquinavir, ritonavir, darunavir or indinavir, (used to treat HIV infection),
- Boceprevir or Telaprevir, (used to treat hepatitis C infection),
- Clarithromycin, telithromycin or erythromycin (used to treat bacterial infections),
- Dabigatran etexilate (used to prevent blood clots),
- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat fungal infections),
- Digoxin (used to treat irregular heartbeats and heart failure),
- Verapamil, diltiazem, nifedipine or amlodipine (used to decrease blood pressure),
- Rosuvastatin, atorvastatin, fluvastatin, simvastatin, pitavastatin or pravastatin (used to lower blood cholesterol),
- Oral contraceptives.

Pregnancy and contraception

Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant. If you become pregnant, stop taking SOVODAK® and tell your doctor immediately.

- If you are pregnant you must not take SOVODAK®.
- SOVODAK® is sometimes used together with ribavirin. Ribavirin can harm your unborn baby. It is therefore very

important that you (or your partner) do not become pregnant during treatment with ribavirin.

- 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 partners become pregnant during SOVODAK® treatment or in the months that follow, you must contact your doctor immediately.

Breast-feeding

It is not known whether Sofosbuvir and Daclatasvir, the active substances, pass into human breast milk. You should not breast-feed during treatment with SOVODAK®.

Driving and using machines

Some patients have reported dizziness, difficulty in concentrating, and vision problems while taking SOVODAK® for their hepatitis C infection. If you have any of these side effects, do not drive or use any tools or machines.

SOVODAK® contains Lactose

If you have been told by your doctor that you have intolerance to some sugars (e.g. lactose), talk to your doctor before taking SOVODAK®.

3. How to take SOVODAK®

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** of SOVODAK®. Swallow the tablets whole. Do not chew or crush the tablet as it has a very unpleasant taste. SOVODAK® can be taken with or without a meal.

Some other medicines can interact with SOVODAK®, affecting the levels of SOVODAK® in your body. If you are taking any of these medicines, your doctor may decide to change your daily dose of SOVODAK® to ensure that the treatment is safe and effective for you.

Since SOVODAK® may be used with other medicines against hepatitis C infection, please read the package leaflets for these medicines. If you have any questions, ask your doctor or pharmacist.

How long to take SOVODAK®

Make sure you take SOVODAK® for as long as your doctor has told you to take it.

The duration of your treatment with SOVODAK® will be either 12 or 24 weeks. The duration of your treatment will depend on whether you have previously received treatment for your hepatitis C infection, the condition of your liver, and what other medicines you will take with SOVODAK®.

If you take more SOVODAK® than you should

If you accidentally take more SOVODAK® tablets than your doctor has recommended, contact your doctor at once or contact the nearest hospital for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

If you forget to take SOVODAK®

It is important not to miss a dose of this medicine.

If you miss a dose of SOVODAK®, take the missed dose as

soon as you remember within the same day. However, if the missed dose is not remembered within the same day, the dose should be skipped and the next dose taken at the appropriate time. Do not take more than 1 dose or double doses in one day.

If you stop taking SOVODAK®

It is important that you continue to take SOVODAK® during the whole treatment period. Otherwise the medicine may not work against the hepatitis C virus. **Do not stop taking SOVODAK® unless your doctor tells you to stop.**

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. Side effects, if present, are usually mild and tolerable.

The most common side effects are headache and fatigue reported in over 10% of subjects. Other less common side effects include nausea, diarrhea and insomnia.

If ribavirin is also taken with SOVODAK®, refer to the drug insert of ribavirin for side effects.

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.

5. How to store SOVODAK®

Keep this medicine out of the sight and reach of children.

Store SOVODAK® protected from light and moisture, at room temperature below 30°C.

Do not use this medicine after the expiry date which is stated on the packaging box and bottle after "EXP". The expiry date is the last day of that month.

Keep in its original bottle.

Do not use if the seal over the bottle opening is broken or missing

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 protect the environment.

6. Contents of the pack and other information

What SOVODAK® contains

- Each film-coated tablet contains 60 mg Daclatasvir (as dihydrochloride) and 400 mg Sofosbuvir

Other ingredients:

- *Tablet core:* Microcrystalline cellulose, Mannitol, Croscarmellose sodium, Silicon dioxide (E551) and Magnesium stearate.

- *Film-coating:* Talc, Titanium Dioxide, PEG, PG, HPMC, Kaolin, Lactose, Iron-Oxide yellow 77492, Yellow lack 18965, Sunset yellow 15985.

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References: BNF 68; the authority on the selection and use of medicines, Sep.2014-Mar.2015, Page 430-431.