

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[HP001 trade name][†]
Sofosbuvir

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly.*

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 questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [HP001 trade name] is and what it is used for
2. What you need to know before you take [HP001 trade name]
3. How to take [HP001 trade name]
4. Possible side effects
5. How to store [HP001 trade name]
6. Contents of the pack and other information

1. What [HP001 trade name] is and what it is used for

[HP001 trade name] is used to treat adults and children who have hepatitis C, an infectious liver disease caused by the hepatitis C virus.

[HP001 trade name] is always taken with other medicines. It is commonly taken with either:

- daclatasvir
- velpatasvir
- ledipasvir

[HP001 trade name] contains the active substance sofosbuvir and works by blocking a protein that the virus needs to grow and reproduce itself. This lowers the amount of hepatitis C virus in your body and removes the virus from your blood over a period of time.

2. What you need to know before you take [HP001 trade name]

Do not take [HP001 trade name]

- 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** (an antibiotic used to treat infections, including tuberculosis);
 - **St. John's wort** (*Hypericum perforatum* – herbal medicine used to treat depression);
 - **Carbamazepine, phenobarbital and phenytoin** (medicines used to treat epilepsy and prevent

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

seizures).

Warnings and precautions

[HP001 trade name] is always taken with other medicines (see section 1 above). Talk to your health care provider before taking this medicine if you:

- Currently take, or have taken in the last few months, the medicine amiodarone to treat irregular heartbeats. Taking [HP001 trade name] with or shortly after amiodarone may make your heart beat too slowly, which can be dangerous. Your health care provider will consider alternative treatments if you have taken amiodarone. If giving [HP001 trade name] with, or shortly after, amiodarone is essential, 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 health care provider 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 [HP001 trade name]. Some patients with diabetes have experienced low sugar levels in the blood (hypoglycaemia) after starting treatment with medicines like [HP001 trade name].

Tell your health care provider immediately if you are taking any medicines for heart problems and during treatment you experience:

- slow or irregular heartbeat, or heart rhythm problems
- shortness of breath or worsening of any shortness of breath you already have
- chest pain
- light-headedness
- palpitations
- fainting

Blood tests

Your health care provider will test your blood before, during and after your treatment with [HP001 trade name]. This is so your health care provider can:

- Decide what other medicines you should take with [HP001 trade name] and for how long;
- Confirm that your treatment has worked and you are free of the hepatitis C virus.

Children and adolescents

The use of [HP001 trade name] in children under 3 years of age has not yet been studied.

Other medicines and [HP001 trade name]

Tell your health care provider if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and medicines obtained without a prescription. [HP001 trade name] must not be used with some medicines (see 'Do not take {DotWP-ProductName}', above) and other medicines may not work as well or may affect the way this medicine works.

Warfarin and other similar medicines called vitamin K antagonists are used to thin the blood. Your health care provider 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 health care provider may need to closely monitor these other medicines you are taking and make adjustments after starting [HP001 trade name].

Talk to your health care provider 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 [HP001 trade name] work less well.

Tell your health care provider if you take:

- amiodarone, used to treat irregular heartbeats. If you are not sure, talk to your health care provider.

Pregnancy and contraception

There are no or limited amount of data on the use of [HP001 trade name] in pregnant women.

If you are pregnant, think you may be pregnant or are planning to become pregnant, ask your health care provider for advice before taking this medicine.

Breast-feeding

You should not breast-feed during treatment with [HP001 trade name]. It is not known whether sofosbuvir, the active substance of [HP001 trade name], passes into human breast milk or could affect the baby.

Driving and using machines

When taking [HP001 trade name] together with other medicines for the treatment of hepatitis C infection, patients have reported tiredness and reduced attention. If you have any of these side effects, do not drive or use any tools or machines.

3. How to take [HP001 trade name]

Always take this medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

[HP001 trade name] should always be taken in combination with other medicines for hepatitis C.

Recommended dose

The recommended dose is **one tablet once a day** for 12 weeks. Your health care provider may extend your treatment with [HP001 trade name] to 24 weeks in certain cases.

How to take the tablet

Swallow the tablet whole **with food**. Do not chew, crush or split the tablet as it has a very bitter taste. Tell your health care provider if you have problems swallowing tablets.

If you are sick (vomit) **less than 2 hours** after taking [HP001 trade name], 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 [HP001 trade name] than you should

If you accidentally take more than the recommended dose you should contact your health care provider or nearest emergency department immediately for advice. Keep the tablet container with you so that you can easily describe what you have taken.

If you forget to take [HP001 trade name]

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

If you do miss a dose:

- **and you notice that there are more than 6 hours to go** until your next dose, you must take the missed tablet right away. Then take the next dose at your usual time.
- **and there are less than 6 hours to go** until the time you usually take [HP001 trade name], then wait and take the next dose at your usual time. Do not take a double dose (two doses close together).

Do not stop taking [HP001 trade name]

Do not stop taking this medicine unless your health care provider 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 health care provider.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

When you take [HP001 trade name] in combination with 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 health care provider if you notice any of the above side effects during therapy.

The following side effects have been reported when [HP001 trade name] has been used in combination with another hepatitis C medicine:

Very common side effects

(may affect more than 1 in 10 people)

- feeling sick (nausea)
- trouble sleeping (insomnia)
- feeling tired and irritable
- headache

Blood tests may also show:

- low haemoglobin (the protein in red blood cells that carries oxygen around the body)
- 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)

- inflammation of the nose and throat (nasopharyngitis)
- loss of appetite
- feeling depressed
- loss of concentration
- shortness of breath, cough
- stomach discomfort, constipation, indigestion
- hair loss and thinning hair
- dry skin and itching
- back pain, muscle spasms
- muscle aches and pains, pain in the joints
- weakness
- fever

Blood tests may also show:

- low red blood cell count (anaemia); the signs may include feeling tired, headaches, shortness of breath when exercising

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 health care provider.

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [HP001 trade name]

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

Do not store above 30°C. Store in the original container.

Do not use this medicine after the expiry date stated on the bottle after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration or that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [HP001 trade name] contains

- The active ingredient is sofosbuvir 400 mg.
- The other ingredients of [HP001 trade name] are:
 - Core tablet:* mannitol, microcrystalline cellulose, croscarmellose sodium, colloidal silicon Dioxide and magnesium stearate
 - Film coat:* polyvinyl alcohol, titanium dioxide, macrogol, talc, iron oxide yellow, iron oxide Red and, ferrosferric oxide/black iron oxide

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [HP001 trade name] looks like and contents of the pack

Peach-coloured, capsule-shaped, film-coated tablets. They are biconvex (rounded on top and bottom) with a beveled edge. The tablets have “SF400” debossed (stamped into the tablet) on one side of the tablet and “M” debossed (stamped into the tablet) on the other side of the tablet.

[HP001 trade name] is available as:

Round, opaque, white plastic (HDPE) bottle, closed with a white, opaque plastic (polypropylene) screw cap with a sachet of desiccant (drying material) inside. Each bottle contains 28 tablets.

Round, opaque, blue plastic (HDPE) bottle, closed with a blue, opaque plastic (polypropylene) screw cap with a sachet of desiccant (drying material) inside. Each bottle contains 28 tablets.

Supplier

Mylan Laboratories Limited
Plot No.564/A/22, Road No. 92, Jubilee Hills
Hyderabad – 500096
Telangana
India
Tel. No.: +91 40 39258109
Email: ProductSafety@viatris.com

Manufacturer

Mylan Laboratories Limited (FDF Unit – 1)
F- 4 & F-12, MIDC, Malegaon
Sinnar, Nashik – 422 113
Maharashtra
India

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in February 2024.

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>