

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/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[HP025 trade name][†]
daclatasvir/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 questions about the medicine, ask your health care provider.
- 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 seem 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 [HP025 trade name] is and what it is used for
2. What you need to know before you take [HP025 trade name]
3. How to take [HP025 trade name]
4. Possible side effects
5. How to store [HP025 trade name]
6. Contents of the pack and other information

1. What [HP025 trade name] is and what it is used for

[HP025 trade name] is used to treat adults with hepatitis C infection. Hepatitis C infection affects the liver and is caused by the hepatitis C virus.

[HP025 trade name] contains daclatasvir and sofosbuvir. Both substances work together to lower the amount of hepatitis C virus in your body and remove the virus from your blood over a period of time.

2. What you need to know before you take [HP025 trade name]

Do not take [HP025 trade name] if you

- Are allergic to daclatasvir, sofosbuvir, or any of the other ingredients of this medicine (see Section 6: Contents of the pack and other information)
- Are taking any of the following medicines:
 - phenytoin, carbamazepine, oxcarbazepine or phenobarbital, used to treat epileptic seizures
 - rifampicin, rifabutin or rifapentine, used to treat tuberculosis
 - dexamethasone, used to treat allergic and inflammatory diseases
 - medicines containing St. John's wort (*Hypericum perforatum*, a herbal preparation used to treat depression)

These medicines lower the effect of [HP025 trade name] and may result in your treatment not working. If you take any of these medicines, tell your health care provider immediately.

Warnings and precautions

Talk to your health care provider before taking this medicine if any of the following apply:

- you currently take, or have taken in the last few months, the medicine amiodarone to treat irregular heartbeats (your health care provider may consider alternative treatments if you have taken this medicine)

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

- you have a current or previous infection with the hepatitis B virus, since your health care provider may want to monitor you more closely
- you have liver problems other than hepatitis C, e.g. if you are awaiting a liver transplantation or if your liver is damaged and is not functioning properly
- you have kidney problems. Talk to your health care provider if you have severe kidney problems or if you are on kidney dialysis.
- you have diabetes. You may need closer monitoring of your blood glucose levels and/or adjustment of your diabetes medication after starting [HP025 trade name]. Some diabetic patients have experienced low sugar levels in the blood (hypoglycaemia) after starting treatment with medicines like [HP025 trade name].

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

- Shortness of breath
- Light-headedness
- Palpitations
- Fainting

Other medicines and [HP025 trade name]

Tell your health care provider if you are taking, have recently taken or might take any other medicines. This is because [HP025 trade name] may affect the way some medicines work. In addition, some medicines may affect the way [HP025 trade name] works. Your health care provider may need to adjust the dose of your medicine or you may not be able to take [HP025 trade name] with certain medicines.

Tell your health care provider if you take any of the following medicines:

- amiodarone or digoxin, used to treat irregular heart beats
- atazanavir/ritonavir, atazanavir/cobicistat, elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil combination tablet, etravirine, nevirapine or efavirenz, used to treat HIV infection
- clarithromycin, telithromycin or erythromycin, used to treat bacterial infection
- warfarin and other similar medicines called vitamin K antagonists, 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.
- dabigatran etexilate, used to prevent blood clots
- ketoconazole, itraconazole, posaconazole or voriconazole, used to treat fungal infections
- verapamil, diltiazem, nifedipine or amlodipine, used to decrease blood pressure
- rosuvastatin, atorvastatin, fluvastatin, simvastatin, pitavastatin or pravastatin, used to lower blood cholesterol
- oral contraceptives

Blood tests

Your health care provider will test your blood before, during and after your treatment with [HP025 trade name]. This is so your health care provider can:

- Decide what other medicines you should take with [HP025 trade name] and for how long
- Confirm that your treatment has worked, and you are free of the hepatitis C virus.

Children and adolescents

[HP025 trade name] is not recommended for patients below 18 years of age. This medicine has not yet been studied in children and adolescents.

Pregnancy and contraception

Tell your health care provider if you or your partner become pregnant, think you may be pregnant or are planning to become pregnant.

If you become pregnant, stop taking [HP025 trade name] and tell your health care provider immediately.

If you can become pregnant, use effective contraception during and for 5 weeks after your treatment with [HP025 trade name].

Breast-feeding

It is not known whether the active substances in [HP025 trade name] pass into human breast milk. You should not breastfeed during treatment with [HP025 trade name].

Driving and using machines

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

Important information about some of the ingredients of [HP025 trade name]

[HP025 trade name] contains lactose. If your health care provider has told that you have an intolerance to some sugars, contact your health care provider before taking [HP025 trade name].

3. How to take [HP025 trade name]

Always take [HP025 trade name] exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Recommended dose

The recommended dose of [HP025 trade name] is one tablet per day.

Swallow the tablet whole. Do not chew, crush or split the tablet as it have a very unpleasant taste. Tell your health care provider if you have problems swallowing tablet. The tablet should be taken with a meal.

If you forget to take [HP025 trade name]

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 [HP025 trade name], 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 [HP025 trade name], wait and take the next dose at your usual time. Do not take a double dose (two doses close together).

If you take more [HP025 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.

How long to take [HP025 trade name]

Make sure you take [HP025 trade name] for as long as your health care provider has told you to take it.

The duration of your treatment with [HP025 trade name] will be either 12 or 24 weeks. The duration of your treatment will depend on the condition of your liver.

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.

The following side effects have been reported:

Very common (may affect more than 1 in 10 people):

- headache, fatigue

Common (may affect up to 1 in 10 people):

- difficulty sleeping
- dizziness
- migraine
- nausea (feeling sick), diarrhoea, abdominal pain
- joint pain, aching or tender muscles, not caused by exercise

When [HP025 trade name] is taken with amiodarone (a medicine used to treat heart problems) or if you have taken amiodarone within the previous six months, you may get one or more of the following side effects:

- Slow or irregular heartbeat or heart rhythm problems
- Shortness of breath or worsening of any shortness of breath that you already have

Tell your health care provider if you notice any of the above side effects during treatment with [HP025 trade name].

Reporting of side effects

If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help improve understanding about the safety of this medicine.

5. How to store [HP025 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 description of the visible signs of deterioration 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 [HP025 trade name] contains

- The active ingredients are daclatasvir (as dihydrochloride) 60 mg and sofosbuvir 400 mg.
- The other ingredients of [HP025 trade name] are anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, polyvinyl alcohol partially hydrolysed, titanium dioxide, macrogol/polyethylene glycol, talc, iron oxide yellow, iron oxide red and iron oxide black.

What [HP025 trade name] looks like and contents of the pack

[HP025 trade name] is a peach coloured, modified, capsule-shaped, biconvex bevelled-edge film-coated tablet debossed with ‘M’ on one side and ‘DTS’ on the other side.

[HP025 trade name] is provided in a round blue opaque HDPE bottle with either a blue opaque polypropylene screw or child resistant cap.

Pack sizes: 28 tablets

Supplier and Manufacturer

Supplier

Mylan Laboratories Limited
Plot No.564/A/22, Road No. 92, Jubilee Hills
Hyderabad – 500096
Telangana
India

Manufacturer

Mylan Laboratories Limited
F- 4 & F-12, MIDC, Malegaon
Sinnar, Nashik – 422 113
Maharashtra
India

E-mail: Imtiyaz.Basade@viatris.com

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

This leaflet was last revised in February 2021

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/pqweb/medicines>