

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

[HP028 trade name][†]
Daclatasvir (dihydrochloride)

*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 [HP028 trade name] is and what it is used for
2. What you need to know before you take [HP028 trade name]
3. How to take [HP028 trade name]
4. Possible side effects
5. How to store [HP028 trade name]
6. Contents of the pack and other information

1. What [HP028 trade name] is and what it is used for

[HP028 trade name] is used to treat adults and children who have hepatitis C, an infectious liver disease caused by the hepatitis C virus.

[HP028 trade name] is always used together with another medicine for hepatitis C infection called sofosbuvir.

[HP028 trade name] contains the active ingredient daclatasvir and 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.

2. What you need to know before you take [HP028 trade name]

Do not take [HP028 trade name] if you:

- are allergic (hypersensitive) to daclatasvir or any of the other ingredients of [HP028 trade name] (listed in section 6)
- are taking (by mouth or other ways that affect the whole body) any of the following medicines:
 - 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)

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

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

Since [HP028 trade name] must always be taken in combination with other medicines against hepatitis C infection, please make sure that you read the “Do not take” section of the patient information leaflets for these medicines. If you are unsure of any information in the patient information leaflets, please contact your health care provider.

Warnings and precautions

Talk to your health care provider before taking [HP028 trade name].

Tell your health care provider if any of the following applies:

- 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)
- you have ever had an infection with another hepatitis virus, hepatitis B, since your health care provider may want to monitor you more closely
- you have previously been treated with [HP028 trade name] or similar hepatitis C medicines containing daclatasvir
- your liver is damaged and not functioning properly (decompensated liver disease)
- you have diabetes. You may need closer monitoring of your blood glucose levels and/or adjustment of your diabetes medication after starting [HP028 trade name]. Some patients with diabetes have experienced low sugar levels in the blood (hypoglycaemia) after starting treatment with medicines like [HP028 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 [HP028 trade name]

Tell your health care provider if you are taking, have recently taken or might take any other medicines. This is because [HP028 trade name] may affect the way some medicines work. In addition, some medicines may affect the way [HP028 trade name] works. Your health care provider may need to adjust the dose of [HP028 trade name] or you may not be able to take [HP028 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, lopinavir/ritonavir, elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil combination tablet or other combinations containing cobicistat, etravirine, nevirapine or efavirenz, used to treat HIV infection
- clarithromycin, telithromycin or erythromycin, used to treat bacterial infections
- 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

With some of these medicines, your health care provider may need to adjust your dose of [HP028 trade name].

Pregnancy and contraception

Tell your health care provider if you are pregnant, think you may be pregnant or are planning to become pregnant. If you become pregnant, stop taking [HP028 trade name] and tell your health care provider immediately.

If you are pregnant you must not take [HP028 trade name].

If you can become pregnant, use effective contraception during and for 5 weeks after your treatment with [HP028 trade name]. As some oral contraceptives may not be suitable for use with [HP028 trade name], discuss suitable contraceptive choices with your health care provider.

Breast-feeding

It is not known whether [HP028 trade name] passes into human breast milk. You should not breast-feed during treatment with [HP028 trade name].

Driving and using machines

Some patients have reported dizziness and tiredness while taking [HP028 trade name] with other medicines for their hepatitis C infection. If you have any of these side effects, do not drive or use any tools or machines.

Other ingredients of [HP028 trade name]

[HP028 trade name] contains lactose. Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

3. How to take [HP028 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.

This medicine is only suitable for patients weighing 26 kg or more.

Recommended dose

The recommended dose of [HP028 trade name] is 1 tablet daily for 12 weeks.

The duration of your treatment with [HP028 trade name] may be extended to 24 weeks in certain cases, depending on whether you have previously received treatment for your hepatitis C infection and the condition of your liver. Your health care provider will tell you if this is the case.

Some other medicines can interact with [HP028 trade name], affecting the levels of [HP028 trade name] in your body. If you have to take any of these medicines, your health care provider may decide to change your treatment to a different product, to ensure that the treatment is safe and effective for you.

Since [HP028 trade name] must always be used with another hepatitis C medicine, sofosbuvir. Please read the patient information leaflets for any other medicines your health care provider recommends with [HP028 trade name]. If you have any questions, ask your health care provider.

How to take this medicine

Make sure you take [HP028 trade name] for as long as your health care provider has told you to take it. Swallow the tablet whole. Do not chew or crush the tablet as it has a very unpleasant taste. [HP028 trade name] can be taken with or without a meal.

If you take more [HP028 trade name] than you should

If you accidentally take more [HP028 trade name] tablets than your health care provider recommended, contact your health care provider at once or contact the nearest hospital for advice. Keep the tablet blister with you so that you can easily describe what you have taken.

If you forget to take [HP028 trade name]

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

If you do miss a dose:

- if you notice up to 20 hours after the time you usually take [HP028 trade name] (that is, there are more than 4 hours to go until your next dose), you must take the missed tablet right away. Then take the next dose at your usual time.
- if there are less than 4 hours to go until the time you usually take [HP028 trade name], then wait and take the next dose at your usual time. Do not take a double dose (two doses close together).

If you stop taking [HP028 trade name]

It is important that you continue to take [HP028 trade name] during the whole treatment period. Otherwise the medicine may not work against the hepatitis C virus. Do not stop taking [HP028 trade name] unless your health care provider told you to stop.

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. Tell your health care provider about any change in your health.

The following side effects have been reported when [HP028 trade name] has been used in combination with other medicines.

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

- low red blood cell count, headache, feeling sick, tiredness

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

- decreased appetite
- irritability
- difficulty sleeping
- dizziness
- migraine
- shortness of breath
- hot flushes
- diarrhoea, vomiting, abdominal pain, heartburn, constipation, wind
- cough, nasal congestion (blocked nose)
- joint pain, aching or tender muscles, not caused by exercise
- dry mouth
- rash, itching, dry skin
- hair loss

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 [HP028 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 remove the desiccant canister from the bottle.

500s count: Discard [HP028 trade name] 30 days after initial opening.

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 a 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 [HP028 trade name] contains

- The active ingredient is daclatasvir (as dihydrochloride).
- The other ingredient(s) of [HP028 trade name] are:

Core tablet:

Anhydrous lactose
Microcrystalline cellulose
Croscarmellose sodium
Colloidal silicon dioxide
Magnesium stearate

Film coat:

Polyvinyl alcohol-partially hydrolysed
Titanium dioxide
Macrogol/PEG
Talc

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

What [HP028 trade name] looks like and contents of the pack

[HP028 trade name] is a white to off-white, round, biconvex film-coated tablet debossed with ‘D’ and ‘6’ on either side of the break line on one side and plain on the other side.

The break line is intended for subdivision of tablets when half a tablet dose is to be administered.

[HP028 trade name] is available as:

28’s Count: White, opaque 60cc /33mm HDPE bottle, containing a 1-gram silica gel canister closed with a 33mm- 400 ARGUS polypropylene child-resistant closure with TEKNIPLEX HS 123 induction sealing wad.

500’s Count: White, opaque 250cc / 53mm HDPE bottle, containing a 1-gram silica gel canister and closed with a cap (53mm- 400 screw polypropylene closure with TEKNIPLEX HS 123 induction sealing wad).

Supplier and Manufacturer

Supplier

Laurus Labs Limited
2nd Floor, Serene Chambers, Road No.7
Banjara hills
Hyderabad
Telangana – 500034
India
Tel. No.: +91-40-3980 4333/23420500
Fax No.: +91-40-3980 4320
Email: rafdf@lauruslabs.com

Manufacturer

Laurus Labs Limited (Unit-II)
Plot No. 19, 20 & 21
Western Sector, APSEZ
Gurajapalem Village,
Rambilli Mandal,
Anakapalli,
Andhra Pradesh 531011
India
Tel. No.: + 91 891 6762100
Fax No.: + 91 891 6762102

“For any information about this medicinal product, please contact the supplier”.

This leaflet was last revised in March 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>