

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

[HP034 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 [HP034 trade name] is and what it is used for
2. What you need to know before you take [HP034 trade name]
3. How to take [HP034 trade name]
4. Possible side effects
5. How to store [HP034 trade name]
6. Contents of the pack and other information

1. What [HP034 trade name] is and what it is used for

[HP034 trade name] is used to treat adults and children who have hepatitis C, an infectious liver disease caused by the hepatitis C virus.

[HP034 trade name] is always used together with another medicine for hepatitis C infection called sofosbuvir.

[HP034 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 [HP034 trade name]

Do not take [HP034 trade name] if you:

- are allergic (hypersensitive) to daclatasvir or any of the other ingredients of [HP034 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 [HP034 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 [HP034 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 [HP034 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 [HP034 trade name]. Some patients with diabetes have experienced low sugar levels in the blood (hypoglycaemia) after starting treatment with medicines like [HP034 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 [HP034 trade name]

Tell your health care provider if you are taking, have recently taken or might take any other medicines. This is because [HP034 trade name] may affect the way some medicines work. In addition, some medicines may affect the way [HP034 trade name] works. Your health care provider may need to adjust the dose of [HP034 trade name] or you may not be able to take [HP034 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 [HP034 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 [HP034 trade name] and tell your health care provider immediately.

If you are pregnant you must not take [HP034 trade name].

If you can become pregnant, use effective contraception during and for 5 weeks after your treatment with [HP034 trade name]. As some oral contraceptives may not be suitable for use with [HP034 trade name], discuss suitable contraceptive choices with your health care provider.

Breast-feeding

It is not known whether [HP034 trade name] passes into human breast milk. You should not breast-feed during treatment with [HP034 trade name].

Driving and using machines

Some patients have reported dizziness and tiredness while taking [HP034 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 [HP033 trade name]

[HP034 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 in other patients. 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.

[HP034 trade name] contains FD&C yellow #6/sunset yellow FCF aluminium lake which may cause allergic reactions.

It is important to consider the contribution of excipients from all the medicines that the patient is taking.

3. How to take [HP034 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 [HP034 trade name] is 1 tablet daily for 12 weeks.

The duration of your treatment with [HP034 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 [HP034 trade name], affecting the levels of [HP034 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 [HP034 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 [HP034 trade name]. If you have any questions, ask your health care provider.

How to take this medicine

Make sure you take [HP034 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. [HP034 trade name] can be taken with or without a meal.

If you take more [HP034 trade name] than you should

If you accidentally take more [HP034 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 [HP034 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 [HP034 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 [HP034 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 [HP034 trade name]

It is important that you continue to take [HP034 trade name] during the whole treatment period. Otherwise the medicine may not work against the hepatitis C virus. Do not stop taking [HP034 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 [HP034 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 [HP034 trade name]

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

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

Do not use this medicine after the expiry date stated on the label, carton and 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 [HP034 trade name] contains

- The active ingredient is 60 mg daclatasvir (as dihydrochloride)
- The other ingredient(s) of [HP034 trade name] are;

Core tablet: Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate.

Film coat: Hypromellose, titanium dioxide, macrogol/PEG, FD&C yellow # 6/sunset yellow FCF aluminium lake

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

What [HP034 trade name] looks like and contents of the pack

[HP034 trade name] is an orange, round, film coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have '60' debossed (stamped into) one side and 'D' debossed (stamped into) on the other side.

[HP034 trade name] is provided in the following packs;

Aluminium foil (Alu/Alu) strip packs, each containing 10 tablets. Available in cartons of 3 x 10 and 10 x 10 tablets.

[HP034 trade name] is also available in round white opaque HDPE bottle containing 28 tablets with a white childproof plastic (polypropylene) screw cap having ribs on sides.

Supplier and Manufacturer

Supplier

Zydus Lifesciences Limited
"Zydus Corporate Park",
Scheme no. 63, survey no. 536,
Khoraj (Gandhinagar), Near. Vaishnodevi circle,
Ahmedabad, Gujarat
India – 382441
E-mail: Drugsafety@zyduslife.com

Manufacturer

Zydus Lifesciences Limited
Kundaim Industrial Estate,
Plot No.203-213, Kundaim,
Goa-403 115
India

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