

Daclavir 60mg Film Coated Tablet

Daclatasvir (60 mg)

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What DAACLAVIR is used for

Daclavir contains the active ingredient daclatasvir. It is used to treat adults with hepatitis C, an infectious disease that affects the liver, caused by the hepatitis C virus.

How DAACLAVIR work?

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.

Daclavir must always be used together with other medicines against hepatitis C infection and must never be used by itself.

Before using DAACLAVIR

-When you must not use it

- if you are allergic to daclatasvir or any of the other ingredients of this medicine
- If you 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 Daclavir and may result in your treatment not working. If you take any of these medicines, tell your doctor immediately.

-Before you start to use it

Talk to your doctor or pharmacist before taking Daclavir.

Tell your doctor if any of the following applies:

- Currently take, or have taken in the last few months, the medicine amiodarone to treat irregular heartbeats (your doctor may consider alternative treatments if you have taken this medicine)
- Infection with the hepatitis B virus
- Liver is damaged and not functioning properly (decompensated liver disease)

-Taking other medicines

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

Do not take Daclavir if you are taking 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 Daclavir so your treatment will not work. If you take any of these medicines, tell your doctor immediately.

Tell your doctor 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 fumarate combination tablet, etravirine, nevirapine or efavirenz, 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 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 doctor may need to adjust your dose of Daclavir.

How to use DAACLAVIR

Always take the medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

-How much to use

The recommended dose of Daclavir is 60 mg once a day. Swallow the tablet whole. Do not chew or crush the tablet as it has a very unpleasant taste. Daclavir can be taken with or without a meal.

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

-When to use it

Follow the direction instructed by your doctor or pharmacist.

-How long to use it

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

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The duration of your treatment with Daclavir 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 Daclavir. You may have to take your other medicines for different lengths of time.

-If you forget to use it

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

If you do miss a dose:

- You notice within 20 hours of the time you usually take Daclavir, you must take the tablet as soon as possible. Then take the next dose at your usual time.
- You notice 20 hours or more after the time you usually take Daclavir, wait and take the next dose at your usual time. Do not take a double dose (two doses close together).

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

-If you use too much (overdose)

If you accidentally take more Daclavir tablets than your doctor recommended, contact your doctor 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.

While you are using DACLAVIR

-Things you must do

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

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

-Things you must not do

Daclavir is not recommended for patients below 18 years of age.

-Things to be careful of

Pregnancy

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

If you are pregnant you must not take Daclavir.

If you can become pregnant, use effective contraception during and for 5 weeks after your treatment with Daclavir.

Daclavir 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 this treatment.

Breastfeeding

It is not known whether Daclatasvir passes into human breast milk. You should not breastfeed during treatment with Daclavir.

Driving and using machines

Some patients have reported dizziness, difficulty concentrating, and vision problems while taking Daclavir 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.

Daclavir contains lactose

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

Side Effects

Like all medicines, Daclavir can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Ask your doctor or pharmacist to answer any questions you may have.

When Daclavir is used together with sofosbuvir (without ribavirin), the following side effects have been reported.

- Headache
- Fatigue
- Nausea

When Daclavir is used together with peginterferon alfa and ribavirin, the following side effects have been reported.

- Headache
- Fatigue
- Pruritus (severe itching of the skin)
- Anaemia (Low red blood cells)
- Influenza-like illness
- Nausea
- Insomnia (sleep disorder)
- Neutropenia (low white blood cells)
- Asthenia (Lack of energy)
- Rash
- Decreased appetite
- Dry skin
- Alopecia (autoimmune disease)
- Myalgia (Pain in muscle)
- Irritability
- Cough
- Diarrhoea
- Dyspnoe (difficult to breath)
- Arthralgia (pain in a joint)

When Daclavir is used together with sofosbuvir and amiodarone and/or other drugs that lower heart rate, the following side effects have been reported.

- Cardiac Arrhythmias (irregular heartbeat)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting).

-Storage

Keep all medicines out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

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Keep container tightly closed in a dry place, below 30°C.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Daclavir 60 mg: the film coated tablet is Green, round biconvex.

-Ingredients

Active ingredient :

Each tablet contains 60 mg daclatasvir (as dihydrochloride)

Inactive ingredients:

Tablet core: Anhydrous lactose, Croscarmellose sodium, Colloidal silicon dioxide, Magnesium stearate and Microcrystalline cellulose.

Tablet film-coat: Hypromellose, Titanium dioxide, Polyethylene glycol, FD&C blue no.2, Yellow iron oxide.

-MAL Number:

MALxxxxxxxxx

Manufacturer

EUROPEAN EGYPTIAN PHARM.
IND.

Amriya, Alexandria, Cairo Desert Road,
P.O Box 111, El Mansheya, Alexandria,
Egypt.

Product Registration Holder

Pharmaniaga Manufacturing Berhad
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