

DASVIR 30/60

Daclatasvir 30mg and 60mg (as dihydrochloride) Tablet

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1. What Dasvir is used for

It is used to treat adults with hepatitis C, an infectious disease that affects the liver, caused by the hepatitis C virus

2. How Dasvir works

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.

3. Before you use Dasvir

-When you must not use it

- Allergic to daclatasvir or any of the other ingredients of this medicine

Pregnancy and lactation

Do not use Dasvir if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not use Dasvir if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to use it

Tell your doctor 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 doctor may consider alternative treatments if you have taken this medicine)
- you have a current or previous infection with the hepatitis B virus, since your doctor may want to monitor you more closely
- your liver is damaged and not functioning properly (decompensated liver disease)

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

- Shortness of breath
- Light-headedness
- Palpitations
- Faintings

-Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. This is because Dasvir may affect the way some medicines work. In addition, some medicines may affect the way Dasvir works. Your doctor may need to adjust the dose of Dasvir or you may not be able to take Dasvir with certain medicines.

Do not take Dasvir 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 Dasvir so your treatment will not work. If you take any of these medicines, tell your doctor immediately.

Tell your doctor or pharmacist if you take any of the following medicines:

- 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
- warfarin and other similar medicines called vitamin K antagonists used to thin the blood. Your doctor may need to increase the frequency of your blood tests to check how well your blood can clot.
- clarithromycin, telithromycin or erythromycin, used to treat bacterial infections
- 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 doctor may need to adjust your dose of Dasvir.

4. How to use Dasvir

-How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Recommended dose

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

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Make sure you take Dasvir for as long as your doctor has told you to take it. The duration of your treatment with Dasvir 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 Dasvir. 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 Dasvir, 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 Dasvir, wait and take the next dose at your usual time. Do

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not take a double dose (two doses close together).

-If you use too much (overdose)

If you accidentally take more Dasvir tablets than your doctor recommended, contact your doctor at once or contact the nearest hospital for advice. Keep the tablet with you so that you can easily describe what you have taken.

5. While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking Dasvir. Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor or pharmacist. Do not give Dasvir to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

6. Side Effects

Like all medicines, Dasvir 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.

Very common

-headache, fatigue

Common

-difficulty sleeping

-dizziness

-migraine

-nausea (feeling sick), diarrhoea, abdominal pain

-joint pain, aching or tender muscles, not caused by exercise

When Dasvir is used together with sofosbuvir and ribavirin, the following side effects have been reported

Very common

-headache, nausea (feeling sick), fatigue
-reduction in red blood cells (anaemia)

Common

-decreased appetite
-difficulty sleeping, irritability
-dizziness
-migraine
-shortness of breath, cough, nasal congestion (blocked nose)
-hot flush
-dry skin, unusual hair loss or thinning, rash, itching
-diarrhoea, vomiting, abdominal pain, constipation, heartburn, excessive gas in the stomach or bowel
-dry mouth
-joint pain, aching or tender muscles, not caused by exercise

When Dasvir is used together with peginterferon alfa and ribavirin the reported side effects are the same as those listed in the package leaflets for these medicines. The most common of these side effects are listed below.

Very common

-decreased appetite
-difficulty sleeping
-headache
-shortness of breath
-nausea
-fatigue
-flu-like illness, fever
-itching, dry skin, unusual hair loss or thinning, rash
-diarrhoea
-cough
-joint pain, aching or tender muscles, not caused by exercise, unusual weakness
-irritability
-reduction in red blood cells (anaemia), reduction in white blood cells

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and Disposal of Dasvir

-Storage

Keep out of the reach and sight of children. Store 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.

8. Product Description

-What it looks like

Dasvir 30 mg: Yellow, round, bevel edged, biconvex, film coated tablets debossed with "D14" on one side and "H" on the other side.

Dasvir 60 mg: Light yellow, round, bevel edged, biconvex, film coated tablets debossed with "D19" on one side and "H" with score line on the other side.

Dasvir 30 mg and 60 mg tablets are available in pack of 28 tablets in a HDPE bottle

-Ingredients

Active Ingredient

Daclatasvir Dihydrochloride

Inactive Ingredients

-Tablet core: anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, silicon dioxide (E551) and magnesium stearate
- Film-coating: hypromellose, titanium dioxide (E171), macrogol 400, yellow iron oxide (E172)

-MAL numbers

Dasvir 30: MALxxxxxxx

Dasvir 60: MALxxxxxxx

9. Manufacturer

HETERO LABS LIMITED, UNIT-V, Sy. No 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Jachcherla Mandal, Mahaboobnagar Dist., Telangana, India.

Product Registration Holder

SYNERRV SDN BHD,
S0-29-2, Menara 1, KL Eco City,
Jalan Bangsar, Kg Haji Abdullah Hukum,
59200 Kuala Lumpur

10. Date of Revision

22nd February 2019

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NPRA(R2)19/26