

MyHep ALL (Sofosbuvir and Velpatasvir Film Coated Tablets 400mg/100mg)

Sofosbuvir & Velpatasvir (400mg/100mg)

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What *MyHep ALL* is used for

MyHep ALL is a medicine that contains the active substances sofosbuvir and velpatasvir in a single tablet. It is given to treat a chronic (long-term) viral infection of the liver called hepatitis C in adults of 18 years and older.

How *MyHep ALL* works

The active substances in this medicine work together by blocking two different proteins that the virus needs to grow and reproduce itself, allowing the infection to be permanently eliminated from the body.

MyHep ALL is sometimes taken with another medicine, ribavirin.

It is very important that you also read the leaflets for the other medicines that you will be taking with *MyHep ALL*. If you have any questions about your medicines, please ask your doctor or pharmacist.

Before you use *MyHep ALL*

When you must not use it

Do not take *MyHep ALL*

- If you are allergic to sofosbuvir, velpatasvir or any of the other ingredients of this medicine.
- **If you are currently taking any of the following medicines:**
 - i. **rifampicin** and **rifabutin** (antibiotics used to treat infections, including tuberculosis);
 - ii. **St. John's wort** (*Hypericum perforatum* – herbal medicine used to treat depression);
 - iii. **carbamazepine, phenobarbital and phenytoin** (medicines used to treat epilepsy and prevent seizures);

Before you start to use it

Warning and precautions

Talk to your doctor if you:

- **have liver problems** other than from hepatitis C, for instance
 - i. **if you have a current or previous infection with the hepatitis B virus**, since your doctor may want to monitor you more closely;
 - ii. **if you have had a liver transplant**
- **have kidney problems**, since *MyHep ALL* has not been fully tested in patients with some severe kidney problems;
- **are taking treatment for human immunodeficiency virus (HIV) infection**, since your doctor may want to monitor you more closely.

Talk to your doctor or pharmacist before taking *MyHep ALL* if:

- 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 diabetes. You may need closer monitoring of your blood glucose levels and/or adjustment of your diabetes medication after starting *MyHep ALL*. Some diabetic patients have experienced low sugar levels in the blood (hypoglycaemia) after starting treatment with medicines like *MyHep ALL*.

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

Blood tests

Your doctor will test your blood before, during and after your treatment with *MyHep ALL*. This is so that:

- Your doctor can decide if you should take *MyHep ALL* and for how long;
- Your doctor can confirm that your treatment has worked, and you are free of the hepatitis C virus.

Taking other medicine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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.

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Your liver function may change with treatment of hepatitis C and therefore may affect other medications (e.g., medicines used to suppress your immune system, etc.). Your doctor may need to closely monitor these other medicines you are taking and make adjustments after starting *MyHep ALL*.

If you are not sure talk to your doctor or pharmacist.

Some medicines should not be taken with *MyHep ALL*.

- **Do not take any other medicine that contains sofosbuvir, one of the active substances in *MyHep ALL*.**

Tell your doctor or pharmacist if you are taking any of the medicines below:

- **amiodarone** used to treat irregular heartbeats;
- **rifapentine** (antibiotic used to treat infections, including tuberculosis);
- **oxcarbazepine** (medicine used to treat epilepsy and prevent seizures)
- **tenofovir disoproxil fumarate** or any medicine containing tenofovir disoproxil fumarate, used to treat HIV infection;
- **efavirenz** used to treat HIV infection;
- **digoxin** used to treat heart conditions;
- **dabigatran** used to thin the blood;
- **modafinil** used to treat sleep disorders;
- **rosuvastatin** or **other statins** used to treat high cholesterol.

Taking *MyHep ALL* with any of these may stop your medicines from working properly or make any side effects worse. Your doctor may

need to give you a different medicine or adjust the dose of medicine you are taking. This change could be to *MyHep ALL* or another medicine you are taking.

- **Get advice from a doctor or pharmacist** if you take medicines used to treat **stomach ulcers, heartburn or acid reflux** as they can decrease the amount of velpatasvir in your blood. These medicines include:

- antacids (such as aluminum/magnesium hydroxide or calcium carbonate). These should be taken at least 4 hours before or 4 hours after *MyHep ALL*;
- proton pump inhibitors (such as omeprazole, lansoprazole, rabeprazole, pantoprazole and esomeprazole). *MyHep ALL* should be taken with food 4 hours before using a proton pump inhibitor.
- H₂-receptor antagonists (such as famotidine, cimetidine, nizatidine or ranitidine). If you need high doses of these medicines, your doctor may give you a different medicine instead or adjust the dose of the medicine you are taking.

These medicines can decrease the amount of velpatasvir in your blood. If you are taking one of these medicines your doctor will either give you a different medicine for stomach ulcers, heartburn or acid reflux, or recommend how and when you take that medicine.

Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age. The use of *MyHep ALL* in children and adolescents has not yet been studied.

Pregnancy and contraception

The effects of *MyHep ALL* during pregnancy are not known. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

MyHep ALL 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 or for a period of time after completing treatment. You must read the "Pregnancy" section in the ribavirin package leaflet very carefully.

Ask your doctor for effective contraception method suitable for you and your partner.

Breast-feeding

Do not breast-feed during treatment with *MyHep ALL*. It is not known whether sofosbuvir or velpatasvir, the two active substances of *MyHep ALL*, pass into human breast milk.

How to use *MyHep ALL*

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to use

The recommended dose is one tablet once a day for 12 weeks.

Swallow the tablet whole with or without food. Do not chew, crush or split the tablet as it has a very bitter taste. The score line is merely for aesthetic purposes and the tablet is not meant to cut into half.

When to use it

If you are taking an antacid, take it at least 4 hours before or at least 4

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hours after *MyHep ALL*.

If you are taking a proton pump inhibitor, take *MyHep ALL* with food 4 hours before using a proton pump inhibitor.

If you are sick (vomit) after taking *MyHep ALL* it may affect the amount of *MyHep ALL* in your blood. This may make *MyHep ALL* work less well.

- If you are sick (vomit) **less than 3 hours after** taking *MyHep ALL*, take another tablet.
- If you are sick (vomit) **more than 3 hours after** taking *MyHep ALL*, you do not need to take another tablet until your next scheduled tablet.

How long to use it

Always take this medicine as prescribed by your doctor. Consult your doctor or pharmacist if you are unsure.

If you forget to use it

It is important not to miss even one dose of this medicine.

If you miss one dose, work out how long it is since you last took *MyHep ALL*:

- If you notice within 18 hours using your *MyHep ALL*, you must take the tablet as soon as possible. Then take the next dose at your usual time.
- If it's 18 hours or more after the time you usually take *MyHep ALL*, wait and take the next dose at your usual time. Do not take a double dose (two doses close together).

If you use too much (overdose)

If you accidentally take more than the recommended dose you should contact your doctor or nearest emergency department immediately for advice. Keep the tablet bottle

with you so that you can easily describe what you have taken.

While you are using it

Things you must do

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Things you must not do

Do not stop taking this medicine unless your doctor tells you to. It is very important that you complete the full course of treatment to give the medicine the best chance to treat your hepatitis C virus infection.

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

Things to be careful of

Driving and using machines
MyHep ALL should not affect your ability to drive or use any tools or machinery.

Side Effects

Like all medicines, this medicine may cause side effects, although not everybody gets them.

Other effects that may be seen during treatment with sofosbuvir:

The frequency of the following side effects is not known (frequency cannot be estimated from the available data).

- a wide spread severe rash with peeling skin which may be accompanied by fever, flu like symptoms, blisters in the mouth, eyes, and/or genitals (Stevens Johnson syndrome).

If you get any side effects tell your doctor.

Report the side-effects if you experience any side effects, talk to

your doctor or pharmacist. This includes any side effects not listed in this brochure.

Common side effects include headache, fatigue and nausea.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of MyHep ALL

Storage

Store below 30°C

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

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

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

What it looks like

Light green to green colored, capsule shaped biconvex beveled edge film coated tablet debossed with 'S and F on either side of score line' on one side and 'M and V on either side of score line' on another side.

Ingredients

- Active ingredient(s)
Sofosbuvir dan velpatasvir

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- Inactive ingredients

*Copovidone, Lactose
Monohydrate, Microcrystalline
Cellulose, Croscarmellose
Sodium, Colloidal Silicon
Dioxide, Magnesium Stearate,
Tabcoat TC Film Coating
Product TC-510031 Green.*

MAL number:

MAL20096010AZ

**Manufacturer and Product
Registration Holder**

Manufacturer

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

Product Registration Holder

Mylan Healthcare Sdn Bhd 15-03 &
15-04, Level 15,
IMAZIUM, No. 8, Jalan SS 21/37,
Damansara Uptown, 47400 Petaling
Jaya Malaysia.

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27 September 2023

Serial Number

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