

Hepatitis C Treatment Information – Initial treatment (Epclusa®/Mavyret™)

You will be taking medication to cure hepatitis C (HCV). The medications for HCV treatment are FDA approved. This guide provides information you will want to know about the medication. It is meant to guide you during treatment and answer questions you may have. Please read this carefully and ask any questions you may have before you begin the medication.

PREGNANCY & BREASTFEEDING WARNING

It is not known if Epclusa® or Mavyret™ will harm an unborn or breastfeeding baby, so it is recommended not to get pregnant or breastfeed while taking this medicine. Women who become pregnant while taking these medications will want to discuss risks versus benefits of continuing treatment with their health care provider. Small studies evaluating the safety of these types of medications in pregnancy have shown high cure rates (100%) and no safety concerns. However, these are small studies and more information is needed before these medications can be recommended for use during pregnancy.

If you will be taking Mavyret™ you will need to stop using ethinyl estradiol-containing medicines (e.g. most birth control pills) before you start treatment. Plan to change to another method of birth control about 2 weeks before starting Mavyret and continuing for 2 weeks after finishing the medication. Progestin-only (e.g. mini pill, Depo shot, Nexplanon™) and barrier contraceptives (condom, diaphragm) are safe to use while taking Mavyret™.

PLEASE NOTE:

It will be important for you to share that you are taking HCV medication with medical, mental health, dental providers, and pharmacist(s) prior to starting any new medications. You must let your provider who is treating your HCV know about any new medications you are prescribed before starting them. This includes vitamins and other supplements.

If you have ever had hepatitis B infection, the virus could become active again during or after taking HCV treatment. You will have blood tests to check for hepatitis B infection before starting treatment (HBsAg). If you have hepatitis B (HBsAg positive), you will have HBV DNA levels (virus count) checked before and while on treatment.

If you have decompensated (severe) liver disease or have ever had liver decompensation you should not take Mavyret.

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YOUR TREATMENT REGIMEN AND INDICATION (for persons who have not had previous treatment)

_____ Epclusa® one tablet daily for 12 weeks:

- ☐ You do not have cirrhosis.
- ☐ You have compensated (mild) cirrhosis.

_____ Epclusa® one tablet daily for 24 weeks:

- ☐ You have decompensated cirrhosis and are ribavirin ineligible.

_____ Mavyret™ three tablets daily for 8 weeks:

- ☐ You do not have cirrhosis.
- ☐ You have compensated (mild) cirrhosis.

DURING TREATMENT

- You will want to call or see your provider if you have any questions or concerns
- Female patients of childbearing potential should use contraception and consider doing a monthly pregnancy test.
- If you are taking medication for diabetes you should monitor for symptoms of low blood sugar. Check your glucose level if not feeling well. Contact your diabetes provider for guidance if your blood sugar is low.
- If you are taking warfarin you may experience changes in your anticoagulation levels. Tell your warfarin prescriber that you are taking HCV medication. Your INR needs to be monitored more frequently on treatment.
- If you have cirrhosis, your provider may order blood tests to monitor for liver injury during treatment.
- Prevent the spread of HCV. Avoid sharing needles, drug works, razors, toothbrushes, or nail clippers. Cover all cuts and clean blood spills with dilute bleach water. If you inject drugs use a syringe service program to get free sterile needles, syringes and other supplies. Use a condom if you are male and have sex with other men.
- Do not drink alcohol or use drugs because these hurt the liver.

AFTER TREATMENT

- **VERY IMPORTANT!!! Three months after completing treatment you will need a blood test to see if you are cured of HCV. There is no way to know if you are cured without this test.**
- If your liver blood levels remain elevated after treatment your provider will want to test for other causes of liver disease like fatty liver.

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- If you have advanced liver fibrosis or cirrhosis prior to treatment you will continue to need a liver ultrasound and alpha fetoprotein (AFP) cancer screening blood test every six months.
- If you have ongoing risk of HCV get a yearly HCV RNA (virus test).

BENEFITS OF TREATMENT

If you have no hepatitis C in your blood 12 weeks **after** the end of treatment, you are cured. Cure of HCV improves quality of life including physical, emotional and social health. Persons who are cured experience many health benefits including decreased liver inflammation and reduced risk for progression of liver fibrosis (scarring). Cirrhosis can resolve and other signs of liver disease improve. There is more than 70% reduction in the risk of liver cancer and 90% reduction in risk of liver related mortality and need for liver transplant. Treatment of HCV also decreases the transmission of infection to others.

It is possible to experience serious side effects on treatment, which will require you to stop the medication. You may still benefit from treatment even if it does not get rid of your hepatitis C, as it may slow down the disease.

To take care of your liver and prevent the spread of hepatitis C

- Do not share needles or other drug works, toothbrushes, razors, or nail clippers.
- Cover cuts to prevent blood exposure.
- Practice safe sex

If you have any questions about treatment, contact the Liver Disease & Hepatitis Program @ 907-729-1560 or your primary care provider.

TREATMENT MEDICATIONS AND SIDE EFFECTS

Epclusa® is a tablet that contains sofosbuvir 400mg and velpatasvir 100mg. Take Epclusa® once daily by mouth with or without food. Store the medication at room temperature. If you miss a dose, take the missed dose as soon as you remember the same day. Do not take more than 1 tablet of Epclusa® in a day. Take your next dose at your regular time the next day.

- **The most common side effects in clinical trials were headache (22%) and feeling tired/fatigue (15%).**

Tell your healthcare provider if you are taking any medicines including prescription and over-the-counter, vitamins, or herbal supplements. Epclusa® and other medications can affect each other and cause you to not have enough or have too much Epclusa® or other medicine in your

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body. The following is a list of some medicines that are known to interact with Epclusa® (this list is not all inclusive):

Stomach/Digestive medicine (for indigestion, heartburn, or stomach ulcers) -

- Proton pump inhibitors are not recommended. If medically necessary omeprazole (Prilosec®) no more than 20 mg daily is okay taken 4 hours after Epclusa®. In this case, Epclusa® should be taken with food. Esomeprazole (Nexium®), lansoprazole (Prevacid®), rabeprazole (Aciphex®), and pantoprazole (Protonix®) have not been studied with Epclusa®.
- Antacids that contains aluminum or magnesium hydroxide (such as Roloids®, Maalox® and Mylanta®) must be taken 4 hours before or 4 hours after you take Epclusa®.
- H2 blockers must be taken at the same time or 12 hours apart from Epclusa®. Famotidine (Pepcid AC®) no more than 40 mg twice daily is okay. Nizatidine (Axid®) and cimetidine (Tagamet®) have not been studied with Epclusa®.

Heart/Cardiovascular medications -

- Amiodarone (Cordarone®, Nexterone®, Pacerone®). When taken with Epclusa® there is risk of slowing heart rate that can cause near-fainting, fainting, dizziness or lightheadedness, extreme tiredness, weakness, shortness of breath, chest pain, confusion, or memory problems). Taking amiodarone with Epclusa is not recommended.
- Digoxin (Lanoxin®). Monitoring of digoxin levels recommended during treatment.
- Warfarin (Coumadin®) Fluctuations of INR values may occur. Frequent monitoring of INR during and post-treatment is recommended.
- Rosuvastatin (Crestor®) No more than 10mg daily is okay. Monitor for muscle pain and weakness.
- Atorvastatin (Lipitor®) Monitor for muscle pain and weakness.

Seizure medications -

- Carbamazepine (Carbatrol®, Epitol®, Equetro®, Tegretol®); Oxcarbazepine (Trileptal®, Oxtellar XR®); Phenytoin (Dilantin®, Phenytek®); Phenobarbital (Luminal®); Primidone (Mysoline®)

HIV/Other Infectious Diseases and medications -

- Efavirenz (ATRIPLA®); Tipranavir (Aptivus®) used in combination with ritonavir (Norvir®)
- Rifabutin (Mycobutin®); Rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®); Rifapentine (Priftin®)
- Regimens containing tenofovir disoproxil fumarate (DF) (ATRIPLA®, COMPLERA®, STRIBILD®, TRUVADA®, VIREAD®). Dosages may need to be adjusted.
- Topotecan (Hycamtin®)

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Herbal supplement –

- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort

Mavyret™ is 3 tablets containing a total daily dose of glecaprevir 300mg and pibrentasvir 120mg. You will take 3 tablets of Mavyret™ by mouth at the same time daily with food. Store the medication at room temperature. Do not miss or skip any doses.

If you miss a dose, take the missed dose as soon as possible that same day. **Exception: If it is less than 6 hours before the next time you are to take Mavyret™ then skip the missed dose. Take the next day's dose at your usual time. Continue taking Mavyret™ daily (3 tablets each day at the same time) until all of your medication is gone.

- **The most common side effects in clinical trials were headache (≈18%) and tiredness (≈15%).**
- **For persons who inject drugs, diarrhea (6%) and nausea (6%) were observed, also.**
- **For persons taking Suboxone®, Sublocade® or naltrexone/Vivitrol®; nausea (11%), and diarrhea (6%) were also observed.**
- **Liver problems may be worsening if you develop nausea, tiredness, yellow skin/eyes, bleeding/bruising more than usual, confusion, poor appetite, diarrhea, brown urine, dark or bloody stool, swelling in the stomach area, or pain in the right upper stomach area or vomiting of blood. If this happens seek care immediately and inform the liver clinic or your provider.**

Do not take the following medications with Mavyret™ (this list may not be all inclusive):

- Rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®). Atazanavir (Reyataz®, Evotaz™)

The following medicines are not recommended to be used with Mavyret™:

- Carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol® XR)
- Ethinyl estradiol-containing medications; combination birth control pills or patches, such as Lo Loestrin™ FE, Norinyl™, Ortho Tri-Cyclen Lo™, Ortho Evra™; hormonal vaginal rings such as NuvaRing®; hormonal replacement therapy medicine Fem HRT™.
- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort
- Efavirenz (ATRIPLA®, Sustiva®); Tipranavir (Aptivus®); Darunavir (Prezista®, Prezcoibix®); Lopinavir (Kaletra®); Ritonavir (Norvir®)
- Cyclosporine (Gengraf®, Neoral®, Sandimmune®)
- Atorvastatin (Lipitor®, Caduet®), Lovastatin (Mevacor®, Altoprev®), Simvastatin (Zocor®, Vytorin®)

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The following medicines require dose adjustment and/or monitoring when taken with Mavyret™:

- Cholesterol lowering medications: Pravastatin (Pravachol®), Rosuvastatin (Crestor®), Fluvastatin (Lescol®), Pitavastatin (Livalo®)
- Digoxin (Lanoxin™, Lanoxicaps®). Dabigatran etexilate (Pradaxa®)
- Warfarin (Coumadin®) Fluctuations of INR values may occur. Frequent monitoring of INR during and post-treatment is recommended.