

Mavyret™ (Glecaprevir/Pibrentasvir) Information Packet

Liver Disease & Hepatitis Program Providers:

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Family Medicine Provider: _____

If you are considering hepatitis C treatment, please read this treatment agreement carefully and be sure to ask any questions you may have before you begin treatment.

The FDA approved glecaprevir combined in three tablets with pibrentasvir (Mavyret™) for the treatment of chronic (lasting 6 months or longer) hepatitis C genotypes 1, 2, 3, 4, 5, and 6.

PREGNANCY & BREASTFEEDING WARNING

It is not known if Mavyret™ will harm an unborn or breastfeeding baby, so it is recommended that women do not get pregnant or breastfeed while taking this medicine.

You must stop using ethinyl estradiol-containing medicines (e.g. some birth control pills) before you start treatment with Mavyret™. If you use these medicines as a method of birth control, you will need to change to another method of birth control during treatment with Mavyret™, and for 2 weeks after finishing treatment with Mavyret™. Progestin-only contraceptives (e.g. mini pill, Depo shot, Nexplanon™) are safe to use during treatment with Mavyret™.

PLEASE NOTE:

You must let your medical, mental health, dental providers, and pharmacist(s) know that you are taking Mavyret™ prior to starting any new medications. You must let Liver Clinic providers 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 Mavyret™. You will have blood tests to check for hepatitis B infection before starting treatment (HBsAg, HBcAb). If you have hepatitis B or are HBcAb or HBsAg positive you will have HBV DNA levels checked before and while on treatment.

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

HOW THE TREATMENT PROCESS WORKS

You will have an appointment monthly while you are taking the medication.

- At each visit blood will be collected.
- A monthly pregnancy test will be done for female patients of childbearing potential.
- Random drug and alcohol tests may be requested.
- Other tests may be done during the treatment if your provider feels there is a need.

Three months after completing treatment you will have an appointment to test for cure of hepatitis C. You may need to see your primary care provider during treatment if you have any other health concerns.

IF YOU HAVE ADVANCED FIBROSIS OR CIRRHOSIS

- **You should continue to have a liver ultrasound and alpha fetoprotein (AFP) cancer screening blood test every six months.**

Liver Clinic Provider, select the appropriate treatment regimen and reason:

____ Mavyret™ will be given for 8 weeks if:

- You have not been previously treated for hepatitis C and do not have cirrhosis or have compensated (mild) cirrhosis (any genotype).
- You have genotype 1, 2, 4, 5, or 6; do not have cirrhosis and were previously treated with a regimen containing interferon, peginterferon, ribavirin and/or sofosbuvir, but no prior treatment experience with a NS5A inhibitor or NS3/4A protease inhibitor.

____ Mavyret™ will be given for 12 weeks if:

- You have genotype 1 with no or compensated (mild) cirrhosis and were previously treated with an NS3/4A protease inhibitor without prior treatment with an NS5A inhibitor.
- You have genotype 1, 2, 4, 5, or 6; have compensated (mild) cirrhosis and were previously treated with a regimen containing interferon, peginterferon, ribavirin, or sofosbuvir, but no prior treatment experience with a NS5A inhibitor or protease inhibitor.

____ Mavyret™ will be given for 16 weeks if:

- You have genotype 1 with no or compensated (mild) cirrhosis and were previously treated with an NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor.
- You have genotype 3; with no or compensated (mild) cirrhosis and were previously treated with a regimen containing interferon, peginterferon, ribavirin, or sofosbuvir, but no prior treatment experience with a NS5A inhibitor or NS3/4A protease inhibitor.

TREATMENT MEDICATIONS AND SIDE EFFECTS

Mavyret™ is 3 tablets containing a total daily dose of glecaprevir 300mg and pibrentasvir 120mg. You will take Mavyret™ once daily by mouth 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. Take the next day's dose at your usual time. **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 dose at your usual time. This will leave you an extra dose at the end of your treatment. Continue taking a single Mavyret™ dose daily (3 tablets each day) until all of your medication is gone.

The most common side effects seen in clinical trials were: headache (≈18%) and tiredness (≈15%).

- For persons who inject drugs, diarrhea (6%) and nausea (6%) were observed, also.
- For persons on medication-assisted treatment (Suboxone®, Sublocade®, naltrexone/Vivitrol®, headache (15%), fatigue (12%), nausea (11%), and diarrhea (6%) were observed.

The following lists are not all inclusive. Medications that are inhibitors or inducers of: P-gp, BCRP, OATP1B1/3, and CYP3A, CYP1A2, and UGT1A1 are not recommended.

Tell your healthcare provider if you are taking any of the following medicines, as they are contraindicated with Mavyret™:

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

Tell your healthcare provider if you are taking any of the following medicines, as they 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®)

Tell your healthcare provider if you are taking any of the following medicines, as they require dose adjustment and/or monitoring:

- 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.

BENEFITS OF TREATMENT

If you have no hepatitis C in your blood 12 weeks **after** the end of treatment, you are cured. Your chance of cure depends on the hepatitis C genotype, how much virus you have in your blood at the beginning of treatment, any past treatment response, how much liver damage you have had prior to treatment, and taking the medication every day.

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

In Clinical Trials/Studies:

Persons with genotype 1, 2, 4, 5, or 6 who did not have cirrhosis were given Mavyret™ for 8 weeks:

- Those with genotype 1 had a 99% (348/351) response rate. (ENDURANCE-1)
- Those with genotype 2 had a 98% (193/197) response. (SURVEYOR-2/ ENDURANCE-5)
- Those with genotype 4 had a 93% (43/46) response. (SURVEYOR -2/ ENDURANCE-5)
- Those with genotype 5 had a 95% (21/22) response. (SURVEYOR -2/ ENDURANCE-5)
- Those with genotype 6 had a 100% (65/65) response. (SURVEYOR -2/ ENDURANCE-5)

Persons with genotype 1, 2, 3, 4, 5, or 6 who were treatment naïve (never treated before) with compensated (mild) cirrhosis were given Mavyret™ for 8 weeks:

- Those with genotype 1 had a 98% (226/231) response rate. (EXPEDITION-8)
- Those with genotype 2 had a 100% (26/26) response. (EXPEDITION-8)
- Those with genotype 3 had a 95% (60/63) response rate. (EXPEDITION-8)
- Those with genotype 4 had a 100% (13/13) response. (EXPEDITION-8)
- Those with genotypes 5 or 6 had a 100% (1/1, 9/9) response. (EXPEDITION-8)

Persons with genotype 3 who were treatment naïve (never treated before) and did not have cirrhosis were treated with Mavyret™ for 8 weeks and had a 95% (149/157) response rate. (ENDURANCE-3)

Those with genotype 3 with or without cirrhosis, previously treated with regimens containing interferon, peginterferon, ribavirin and/or sofosbuvir were given Mavyret™ for 16 weeks and had a 96% (66/69) response rate. Those without cirrhosis had a 95% (21/22) response and those with cirrhosis had a 96% (45/47) response. (SURVEYOR-2)

Persons with genotype 1 with no or compensated (mild) cirrhosis, previously treated with an NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor were given Mavyret™ for 16 weeks and had a 94% (16/17) response rate. (MAGELLAN-1)

Persons with genotype 1 with no or compensated (mild) cirrhosis, previously treated with an NS3/4A protease inhibitor without prior treatment with an NS5A inhibitor were given Mavyret™ for 12 weeks and had a 92% (23/25) response rate. (MAGELLAN-1)

Persons who identified with current or recent injection of drugs, treatment response rate was 89%.

Persons who identified with past injection drug use (not current/recent use), had a 98% response rate.

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.
- Only get a tattoo if the equipment and ink used is sterile (such as at a commercial, regulated tattoo studio).
- Practice safe sex.
- Do not drink alcohol or use drugs because these hurt the liver.

WHOM TO CALL

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

Mavyret™ (Glecaprevir /Pibrentasvir) Treatment Medication

- Take all 3 pink oblong tablets at the same time every day with food.
- The generic name for **Mavyret™** is glecaprevir 100mg and pibrentasvir 40mg. The total daily dose is glecaprevir 300mg and pibrentasvir 120 mg.

Pick up refills for **Mavyret™** after monthly appointments.

For Specialty Pharmacy refills, call: _____

On these dates: _____

Call _____ to schedule your family medicine treatment appointments, or if you have any other health concerns.

Call Liver Clinic (907-729-1560) if you feel you are having any significant side effects while taking these medications, or have any other questions about treatment.

*****For any emergencies after normal business hours, please go to the Emergency Room. Make sure any healthcare provider you see knows you are on treatment. Carry a list of your medicines with you.**

For more information on managing side effects visit our website at <http://anthc.org/hep>