

Zepatier™ (Elbasvir/Grazoprevir) 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 elbasvir combined with grazoprevir in one tablet (Zepatier™) for the treatment of hepatitis C genotype 1 and 4.

PREGNANCY & BREASTFEEDING WARNING

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

PLEASE NOTE

You must let your medical, mental health, dental providers, and pharmacist(s) know that you are taking Zepatier™ 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 Zepatier™. 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.

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 will then be seen yearly (corresponding to your end of treatment date) for the next 5 years. 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.**
- You will have an additional appointment in Liver Clinic 6 months after completing treatment.

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

____ Zepatier™ will be given for 12 weeks if:

- You have genotype 1a and do not have baseline NS5A polymorphisms (mutations in the hepatitis C virus that can decrease response to treatment).
- You have genotype 1b.
- You have genotype 4 without or with compensated (mild) cirrhosis.
- You have genotype 4 without or with compensated (mild) cirrhosis and relapsed after treatment with pegylated interferon and ribavirin.

TREATMENT MEDICATIONS AND SIDE EFFECTS

Zepatier™ is a fixed-dose combination tablet containing elbasvir 50mg and grazoprevir 100mg. You will take Zepatier™ 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 Zepatier™ in a day. Take your next dose at your regular time the next day.

- **The most common side effects are tiredness (11%), headache (11%), & nausea (11%).**
- There is a 1% risk of ALT (a liver enzyme) elevation >5x upper limit of normal. Your blood work will be monitored monthly for this.

Tell your healthcare provider if you are taking any of the following medicines, as they are **contraindicated with Zepatier™** (this list is not all inclusive; medications that are OATP1B1/3 inhibitors or strong CYP3A inducers are contraindicated):

- Phenytoin (Dilantin®), (Phenytek®)
- Carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol® XR)
- Rifampin (Rifadin®, Rifamate®, Rifater®, Rimactane®)
- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort
- Efavirenz (ATRIPLA®, Sustiva®); Tipranavir (Aptivus®); Atazanavir (Reyataz®, Evotaz™); Darunavir (Prezista®, PrezcoBix®); Lopinavir (Kaletra®); Saquinavir (Invirase®)
- Cyclosporine (Gengraf®, Neoral®, Sandimmune®)

Tell your healthcare provider if you are taking any of the following medicines, as they are not recommended to be used with Zepatier™ (this list is not all inclusive; medications that are moderate CYP3A inducers are not recommended):

- Nafcillin
- Ketoconazole
- Bosentan (Tracleer®)
- Modafinil (Provigil®)
- Cobicistat containing regimens: elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate or alafenamide (Stribild®, Genvoya®)
- Etravirine (Intelence®)

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

- Tacrolimus (Astagraf XL®, Envarsus XR™, FK506 (common name), Hecoria™, Prograf®)
- Cholesterol lowering medications: atorvastatin (Lipitor®, Caduet®), rosuvastatin (Crestor®), fluvastatin (Lescol®), lovastatin (Mevacor®, Altoprev®), simvastatin (Zocor®)
- 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 1a who did not have pretreatment NS5A polymorphisms and those with genotype 1b who were treated with Zepatier™ for 12 weeks had a 99% (131/135 and 129/131 respectively) response (cure) rate. The response rate in persons with mild cirrhosis was 97% (of 92 patients). (C-EDGE TN)

Persons with severe renal disease treated with Zepatier™ for 12 weeks had an overall 94% (115/122) response rate. Those with compensated (mild) cirrhosis had an 86% (6/7) response rate. (C-SURFER) This regimen was not studied in persons with genotype 4 with severe renal disease, but the response is expected to be similar.

Persons with genotype 4 who took Zepatier™ for 12 weeks had a 97% (64/66) response rate (C-SCAPE, C-EDGE).

Persons with genotype 4 who relapsed after pegylated interferon and ribavirin treatment were treated with Zepatier for 12 weeks and had a 100% (2/2) response (C-EDGE TE).

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.

Zepatier™ Treatment Medication

You will take **Zepatier™ (elbasvir 50mg/grazoprevir 100mg)**

Take ONE tablet by mouth daily, with or without food.

The generic name for Zepatier™ is elbasvir 50 mg/grazoprevir 100mg.

- Do not take supplements or tea containing St. John’s wort while taking Zepatier™.

Pick up refills for **Zepatier™** 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 www.anthc.org/hep