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Glecaprevir and Pibrentasvir

pronounced as (glek a' pre vir)(pi brent' as vir)

IMPORTANT WARNING:

You may already be infected with hepatitis B (a virus that infects the liver and may cause severe liver damage) but not have any symptoms of the disease. In this case, taking the combination of glecaprevir and pibrentasvir may increase the risk that your infection will become more serious or life-threatening and you will develop symptoms. Tell your doctor if you have or ever had a hepatitis B virus infection. Your doctor will order a blood test to see if you have or have ever had hepatitis B infection. Your doctor will also monitor you for signs of hepatitis B infection during and for several months after your treatment. If necessary, your doctor may give you medication to treat this infection before and during your treatment with the combination of glecaprevir and pibrentasvir. If you experience any of the following symptoms during or after your treatment, call your doctor immediately: excessive tiredness, yellowing of the skin or eyes, loss of appetite, nausea, vomiting, pale stools, pain in upper right side of the stomach area, or dark urine.

Keep all appointments with your doctor and the laboratory. Your doctor may order certain tests before, during, and after your treatment to check your body's response to the combination of glecaprevir and pibrentasvir.

Talk to your doctor about the risks of taking glecaprevir and pibrentasvir.

Why is this medication prescribed?

The combination of glecaprevir and pibrentasvir is used to treat certain types of chronic (long-term) hepatitis C infection (swelling of the liver caused by a virus) in adults and children 3 years of age and older. It is also used to treat certain types of chronic hepatitis C infection in adults and children 3 years of age and older who have already received another medication to treat their hepatitis C infection. Glecaprevir is in a class of medications called HCV NS3/4A protease inhibitors. It works by decreasing the amount of hepatitis C virus (HCV) in the body. Pibrentasvir is in a class of medications called HCV NS5A inhibitors. It works by stopping the virus that causes hepatitis C to spread inside the body.

How should this medicine be used?

The combination of glecaprevir and pibrentasvir comes as a tablet or pellets to take by mouth. It is usually taken with food once daily for 8 to 16 weeks. Your doctor will tell you how many tablets or packets of pellets to take for each dose. Take glecaprevir and pibrentasvir at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take glecaprevir and pibrentasvir exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Glecaprevir and pibrentasvir pellets should be taken with soft foods without chewing. To prepare a dose of glecaprevir and pibrentasvir pellets with soft food, sprinkle the entire contents of packets of pellets in a bowl or cup on a small amount of soft food such as peanut butter, chocolate hazelnut spread, cream cheese, jam, or greek yogurt. Do not mix the pellets with liquid or foods that may slide off the spoon to prevent the medicine from dissolving too fast. Give the entire mixture within 15 minutes of sprinkling the pellets on food. If pellets stick to the bowl or cup, add a small amount of soft food and swallow the rest of the mixture. To avoid a bitter aftertaste, the pellets should not be chewed or dissolved in the food.

Continue to take glecaprevir and pibrentasvir even if you feel well. The length of your treatment depends on your condition, if you have previously taken certain HCV medications, how well you respond to the medication, and whether you experience serious side effects. Do not stop taking glecaprevir and pibrentasvir without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking glecaprevir and pibrentasvir,

- tell your doctor and pharmacist if you are allergic to glecaprevir, pibrentasvir, any other medications, or any of the ingredients in the glecaprevir and pibrentasvir tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor if you are taking atazanavir (Reyataz, in Evotaz) or rifampin (Rifadin, Rimactane, in Rifamate, in Rifater). Your doctor will probably tell you not to take glecaprevir and pibrentasvir if you are taking one of these medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: anticoagulants ('blood thinners') such as warfarin (Coumadin, Jantoven); carbamazepine (Carbatrol, Epitol, Equetro, Tegretol), cholesterol-lowering medications (statins) such as atorvastatin (Lipitor, in Caduet), fluvastatin (Lescol), lovastatin (Altoprev), pitavastatin (Livalo), pravastatin (Pravachol), rosuvastatin (Crestor), and simvastatin (Zocor, in Simcor, in Vytorin); cyclosporine (Gengraf, Neoral, Sandimmune); dabigatran (Pradaxa); digoxin (Lanoxin); ethinyl estradiol oral contraceptives such as certain ('birth control pills'), patches, hormonal vaginal rings, and other ethinyl estradiol products; certain hormone replacement therapies (HRT); and certain medications for human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) including darunavir (Prezista, in Prezcofix), efavirenz (Sustiva, in Atripla), lopinavir (in Kaletra), or ritonavir (Norvir, in Kaletra); and phenytoin (Dilantin, Phenytek). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have any type of liver disease other than hepatitis C. Your doctor may tell you not to take glecaprevir and pibrentasvir.
- tell your doctor if you have or have ever had human immunodeficiency virus (HIV) or diabetes, or if you have ever received a liver or kidney transplant.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking glecaprevir and pibrentasvir, call your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If it is 18 hours or less after you miss a dose of glecaprevir and pibrentasvir, take the missed dose with food as soon as you remember it. However, if it is more than 18 hours since the time you should have taken your dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Glecaprevir and pibrentasvir may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- tiredness
- weakness
- nausea
- diarrhea
- itching

Glecaprevir and pibrentasvir may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

- sleepiness
- confusion
- swelling of stomach area
- vomiting blood or material that looks like coffee grounds
- dark, black, or bloody stools

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Mavyret[®]

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