

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

 **ZEPATIER®**

50 mg of elbasvir and 100 mg of grazoprevir

Read this carefully before you start taking **ZEPATIER®** and each time you get a refill. Some of the information may have changed. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ZEPATIER®**.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

Your doctor might also want you to take **ZEPATIER®** with ribavirin or sofosbuvir. It is very important that you also read the patient product information for these other medicines if you are taking either of them with **ZEPATIER®**.

If you have any questions about your medicines, please ask your doctor or pharmacist.

Serious Warnings and Precautions

Hepatitis B activity (inflamed liver) may increase when taking antiviral drugs like **ZEPATIER®**, sometimes leading to liver failure and death. (see the “To help avoid side effects...” section, Hepatitis B Reactivation)

What is **ZEPATIER® used for?**

ZEPATIER® is used for the treatment of chronic (lasting a long time) hepatitis C virus genotypes 1, 3, and 4 infection in adults 18 years of age and older. Your treatment regimen will depend on the type of hepatitis C virus you have, whether or not you have cirrhosis (liver scarring) and your treatment history. Your doctor will decide if this drug is right for you.

How does **ZEPATIER® work?**

Patients with hepatitis C infection have the virus in their blood and in their liver.

ZEPATIER® blocks two different proteins from the virus that are needed to make new viruses, and this helps to clear the virus from the body in most people.

What are the ingredients in **ZEPATIER®?**

Medicinal ingredients: elbasvir and grazoprevir

Non-medicinal ingredients: colloidal silicon dioxide, copovidone, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, mannitol, microcrystalline cellulose, sodium chloride, sodium lauryl sulfate, vitamin E polyethylene glycol succinate.

The tablets are film-coated with a coating material containing the following inactive ingredients: carnauba wax, ferrosoferric oxide, hypromellose, iron oxide red, iron oxide yellow, lactose monohydrate, titanium dioxide and triacetin.

ZEPATIER® comes in the following dosage form:

ZEPATIER® (elbasvir 50 mg and grazoprevir 100 mg)

The film-coated tablets are beige oval-shaped with the number 770 on it.

Do not use ZEPATIER® if:

- are allergic to elbasvir, grazoprevir or any of the other ingredients of ZEPATIER®. See **What are the ingredients in ZEPATIER®?** for a complete list of ingredients.
- have moderate or severe liver problems.
- you are taking any of the following medicines:
 - rifampin for tuberculosis
 - HIV protease inhibitors such as atazanavir, darunavir, lopinavir, saquinavir, or tipranavir
 - efavirenz (Sustiva*) or etravirine (Intelence*) for HIV
 - cyclosporine to stop organ transplant rejection
 - carbamazepine (Tegretol*) or phenytoin (Dilantin*): medicines for epilepsy and seizures
 - St. John's wort (*Hypericum perforatum*, a herbal medicine) for depression or other problems.

If you are using ZEPATIER® with ribavirin or sofosbuvir, read the patient information for the other products for further directions when not to use these medications.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZEPATIER®. Talk about any health conditions or problems you may have, including if you:

- have ever taken any medicine for hepatitis C.
- have had, or are waiting for, a liver transplant.
- have any other medical conditions.
- are pregnant, or plan to become pregnant, breastfeed or plan to breastfeed.

Hepatitis B Reactivation:

Taking antiviral drugs such as ZEPATIER® may increase hepatitis B activity. This can lead to liver problems such as liver failure and death. Contact your doctor if:

- you have never been tested for hepatitis B
- you know you have a current hepatitis B infection
- you have had a previous hepatitis B infection

Your healthcare professional may do blood tests:

- before hepatitis C treatment
- to see the hepatitis B levels in your blood
- and may order hepatitis B treatment

Your doctor may monitor your blood test results during ZEPATIER[®] treatment if you have some conditions, for example, to check:

- how well your blood can clot if you take warfarin (Coumadin*) or other similar medicines called vitamin K antagonists, to thin the blood.
- blood sugar levels if you have diabetes.
- immunosuppressant drug levels if you receive immunosuppressive therapy.

Liver Issues:

Talk to your doctor if you had or have liver problems other than hepatitis C infection. Your doctor may order medical tests to determine how your liver is functioning. Tell your doctor right away if you experience symptoms of liver failure such as:

- abdominal pain or pressure, fluid in your abdomen.
- bleeding or bruising more easily than normal.
- confusion, difficulty concentrating, loss of consciousness, sleepiness, tiredness, weakness.
- nausea, vomiting, diarrhea.
- dark or bloody stools, dark or brown (tea coloured) urine.
- yellowing of the skin and eyes.
- vomiting of blood.
- loss of appetite.

Your doctor will decide if ZEPATIER[®] is right for you.

Other warnings you should know about:

Pregnancy and Birth Control

- Tell your doctor if you are pregnant or plan to become pregnant.
- We don't know if ZEPATIER[®] will harm your baby while you are pregnant.

ZEPATIER[®] may be used with ribavirin. Ribavirin may cause birth defects and death of the unborn baby. Extreme care must be taken to avoid becoming pregnant.

- Females must have a negative pregnancy test before starting ZEPATIER[®] and ribavirin, every month while on the medicine, and for 6 months after stopping them.
- You or your partner should not become pregnant while taking ZEPATIER[®] with ribavirin and for 6 months after you have stopped taking them.
- You and your partner must use 2 kinds of birth control while taking ZEPATIER[®] and ribavirin and for 6 months after you have stopped taking them.

- Talk to your doctor about the kind of birth control that you can use.
- If you or your partner becomes pregnant while taking ZEPATIER[®] and ribavirin or within 6 months after you stop taking them, tell your doctor right away.

Breast-feeding

- Tell your doctor if you are breastfeeding or planning to breastfeed.
- We don't know if ZEPATIER[®] gets in your breast milk and gets passed to your baby.
- It is recommended that you do not breastfeed while taking ZEPATIER[®].
- Read the ribavirin package leaflet for important breastfeeding information.

Tell your healthcare professional about all the medicines you take, including any prescription and non-prescription drugs, vitamins, minerals, natural and herbal supplements or alternative medicines.

ZEPATIER[®] and other medicines may affect each other.

The following medicines may interact with ZEPATIER[®]:

Do not take ZEPATIER[®] and tell your doctor if you are taking any of the following medicines:

- bosentan (Tracleer*): for pulmonary arterial hypertension
- modafinil (Alertec*): to help people who cannot stay awake

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

- oral ketoconazole: to treat fungal infections
- tacrolimus: to stop organ transplant rejection
- elvitegravir, cobicistat, emtricitabine and tenofovir: a drug combination to treat HIV
- sunitinib (to treat certain cancers)
- warfarin and other similar medicines called vitamin K antagonists
- medicines to treat diabetes

Tell your doctor or pharmacist if you take any of the following medicines for lowering blood cholesterol:

- atorvastatin (Lipitor*)
- fluvastatin (Lescol*)
- lovastatin
- rosuvastatin (Crestor*)
- simvastatin (ZOCOR[®])

Also see “**Do not use ZEPATIER® if**”.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking ZEPATIER®.

How to take ZEPATIER®:

Take ZEPATIER® exactly as your doctor tells you to take it.

- ZEPATIER® comes in a blister pack of individually-packaged pills. Be sure to keep the pills in this pack until you are ready to take your medicine.
- You can take ZEPATIER® with or without food.
- Do not stop taking ZEPATIER® without first talking with your doctor.

Usual adult dose:

Take one tablet a day at the same time every day. Your doctor will tell you for how many weeks you should take ZEPATIER®.

Overdose:

If you think you have taken too much of ZEPATIER®, contact your healthcare professional or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

It is important not to miss a dose of this medicine. If you do miss a dose, work out how long it is since you should have taken ZEPATIER®:

- If it has been less than 16 hours since you should have taken your dose, take the missed dose as soon as possible. Then take your next dose at your usual time.
- If it has been more than 16 hours since you should have taken your dose, do not take the missed dose. Wait and take the next dose at your usual time.
- Do not take a double dose (two doses together) to make up for a forgotten dose.

What are possible side effects from using ZEPATIER®?

These are not all the possible side effects you may feel when taking ZEPATIER®. If you experience any side effects not listed here, contact your healthcare professional. Please also see **Other warnings you should know about.**

Very common side effects of ZEPATIER® (more than 10%):

- headache.
- feeling tired.

Common side effects of ZEPATIER® (1-10%):

- abdominal pain.
- constipation.
- diarrhea.
- dry mouth.
- vomiting.
- nausea.
- weakness.
- decreased appetite.
- joint pain.
- muscle pain.
- dizziness.
- anxiety.
- depression.
- difficulty sleeping.
- irritability.
- hair loss.
- itching.

Common and very common side effects of ZEPATIER® when used with ribavirin:

- headache.
- feeling tired or weak.
- nausea or vomiting.
- itching.
- muscle aches.
- rash.
- trouble sleeping.
- low red blood cell counts.
- shortness of breath.
- indigestion.
- feeling less hungry.
- cough.
- feeling irritable.

Common side effects of ZEPATIER® when used with sofosbuvir:

- headache.
- nausea.
- diarrhea.
- feeling tired.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Frequency Unknown <u>Hepatic decompensation and hepatic failure (liver failure):</u> abdominal pain or pressure, fluid in your abdomen, bleeding or bruising more easily than normal, confusion, difficulty concentrating, loss of consciousness, sleepiness, tiredness, weakness, nausea, vomiting, diarrhea, dark or bloody stools, dark or brown (tea coloured) urine, yellowing of the skin and eyes, vomiting of blood, loss of appetite		✓	

Your doctor will do blood tests to check how your liver is working before and while you are taking ZEPATIER®.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.</p> <p>3 ways to report:</p> <ul style="list-style-type: none"> • Online at MedEffect; • By calling 1-866-234-2345 (toll-free); • By completing a Consumer Side Effect Reporting Form and sending it by: <ul style="list-style-type: none"> - Fax to 1-866-678-6789 (toll-free), or - Mail to: Canada Vigilance Program Health Canada, Postal Locator 1908C Ottawa, ON K1A 0K9 <p>Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.</p> <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>

Storage:

- Keep ZEPATIER[®] in its original blister pack until you are ready to take it. Do not take the pills out of the original blister pack to store in another container such as a pill box. This is important because the pills are sensitive to moisture. The pack is designed to protect them.
- Keep ZEPATIER[®] at room temperature (15°C - 30°C). Protect from moisture.

Keep out of reach and sight of children.

If you want more information about ZEPATIER[®]:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#) or Merck Canada website www.merck.ca or by calling Merck Canada at 1-800-567-2594.

To report an adverse event related to ZEPATIER[®], please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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