

ZEPATIER[®] Film-coated Tablets

Grazoprevir/ Elbasvir (100mg/50mg)

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What ZEPATIER is used for

ZEPATIER is used for the treatment of chronic (lasting a long time) hepatitis C virus genotypes 1 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 ZEPATIER works

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.

Before you take ZEPATIER

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. 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 “*Before you start to take it*” section, Hepatitis B Reactivation)

- *When you must not take it*

Do not use ZEPATIER if you:

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

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

Pregnancy

- 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.

- *Before you start to take it*

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 liver problems other than hepatitis C infection.
- have had, or are waiting for, a liver transplant.

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- 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

Tell your doctor right away if you develop the following symptoms of liver problems such as:

- loss of appetite.
- nausea and vomiting.
- feeling tired and weak.
- abdominal pain.
- yellowing of your skin or eyes.
- colour changes in your stool.

Your doctor will decide if ZEPATIER is right for you.

- Taking other medicines

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: for pulmonary arterial hypertension
- modafinil: 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

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

- atorvastatin
- fluvastatin
- lovastatin
- rosuvastatin
- simvastatin

Also see "*When you must not take it*".

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.

- How much to take

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.

- When to take it

Use as directed by your doctor or pharmacist.

- How long to take it

Continue taking ZEPATIER for as long as your doctor recommends.

- If you forget to take it

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.

- If you take too much (overdose)

If you think you have taken too much of ZEPATIER, contact your healthcare professional immediately, even if there are no symptoms.

While you are taking ZEPATIER

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking ZEPATIER.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines

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without consulting your doctor.

Do not give ZEPATIER to anyone else, even if they have the same symptoms or condition as you.

*- Things to be careful of
Driving and using machines*

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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 *When you must not take it*.

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.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI)

Storage and Disposal of ZEPATIER*- Storage*

- Keep out of the reach and sight of children.
- Store below 30°C. Store ZEPATIER in the original blister package until use to protect from moisture

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description*- What it looks like*

ZEPATIER comes in the following dosage form:

ZEPATIER (grazoprevir 100 mg and elbasvir 50 mg)

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

- Ingredient

Active Ingredients:

The active substances are grazoprevir and elbasvir

Inactive ingredients:

sodium lauryl sulfate, vitamin E polyethylene glycol succinate, copovidone, hypromellose, microcrystalline cellulose, mannitol, lactose monohydrate, croscarmellose sodium, sodium chloride, colloidal silicon dioxide, and magnesium stearate. The tablets are film-coated with a coating material containing the following inactive ingredients: lactose monohydrate, hypromellose, titanium dioxide, triacetin, iron oxide yellow, iron oxide red, ferrousferrous oxide, and carnauba wax.

- MAL number

MAL20172943AZ

Manufacturer

MSD International GmbH
Ballydine, Kilsheelan
Clonmel, Co. Tipperary
Ireland

Product Registration Holder

Merck Sharp & Dohme (Malaysia) Sdn. Bhd.
Lot No. B-22-1 & B-22-2, Level 22
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Date of Revision

10/08/2017 (Version 032017)

Serial Number

BPFK (R1) 17/010