

ZEPATIER®

Elbasvir / grazoprevir

Consumer Medicine Information

What is in this leaflet?

Read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed.

This leaflet answers some common questions about ZEPATIER tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ZEPATIER against the benefits they expect it will have for you.

Your doctor might also want you to take ZEPATIER with ribavirin. It is very important that you also read the Consumer Medicine Information for ribavirin if you are taking it with ZEPATIER.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again. Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What ZEPATIER is used for?

ZEPATIER is one tablet that contains two active substances called elbasvir and grazoprevir. ZEPATIER is used to treat chronic (long-lasting) hepatitis C infection in adults.

This medicine belongs to a group of medicines called direct-acting antivirals.

How ZEPATIER works

Hepatitis C is a virus that infects the liver. This medicine works by lowering the amount of Hepatitis C virus in your body. The active substances in ZEPATIER work together by blocking two different proteins that the hepatitis C virus needs to make more virus.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use ZEPATIER

When you must not take ZEPATIER

Do not take ZEPATIER if you:

- are allergic to elbasvir, grazoprevir or any of the other ingredients of ZEPATIER. See the section on "Ingredients" at the end of this Consumer Medicine Information for a complete list of ingredients in ZEPATIER.
- have certain liver problems
- you are taking any of the following medicines:
 - carbamazepine or phenytoin, for epilepsy and seizures
 - cyclosporine to stop organ transplant rejection
 - efavirenz, atazanavir, darunavir, lopinavir,

saquinavir or tipranavir for HIV

- rifampicin for tuberculosis
- St. John's wort (Hypericum perforatum, a herbal medicine) for depression or other problems

Do not take ZEPATIER if the packaging is torn or shows signs of tampering.

Do not take ZEPATIER after the expiry date (EXP) printed on the pack has passed.

Before you start to take ZEPATIER

Tell your doctor if you:

- have ever had hepatitis B
- have ever taken any medicine for hepatitis C
- have liver problems other than hepatitis C
- have had, or are waiting for, a liver transplant
- have any other medical conditions
- are pregnant, trying to get pregnant, breastfeeding or planning to breastfeed.

Your doctor will decide if ZEPATIER is right for you.

Tell your doctor or pharmacist if you are pregnant or trying to get pregnant.

It is not known if taking ZEPATIER while you are pregnant will harm your unborn baby. Your doctor can discuss the risks and benefits involved.

Do not take ZEPATIER in combination with ribavirin if you

or your partner is pregnant or planning to become pregnant.

It is very important that you or your partner avoid becoming pregnant during treatment and for 6 months after stopping treatment with ribavirin. Read the ribavirin Consumer Medicine Information for important pregnancy, contraception and breast feeding information. If you (or your partner) do become pregnant while taking ribavirin or within six months after you stop taking ribavirin, tell your doctor straight away.

Tell your doctor or pharmacist if you are breastfeeding or are planning to breastfeed.

It is not known if ZEPATIER can be passed to your baby in your breast milk. Your doctor can discuss the risks and benefits involved.

You can obtain further information from your doctor or pharmacist, who has more detailed information.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

You must also tell any doctor that is prescribing medicine to you about all the medicines you take, including ZEPATIER, other prescription and non-prescription medicines, vitamins and herbal supplements.

ZEPATIER may affect the way other medicines work, and other medicines may affect how ZEPATIER works.

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.

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

- bosentan for pulmonary arterial hypertension
- cobicistat, elvitegravir, emtricitabine and tenofovir combination treatment for HIV

- etravirine for HIV
- oral ketoconazole for fungal infections
- modafinil to help people who cannot stay awake
- nafcillin for an infection
- rosuvastatin, atorvastatin, fluvastatin, simvastatin, or lovastatin, for lowering blood cholesterol
- sunitinib for treatment of certain cancers
- tacrolimus to prevent organ transplant rejection
- warfarin and other similar medicines called vitamin K antagonists
- medicines to treat diabetes

Your doctor may have to change your medicines or change the dose of your medicines.

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

Use in Children

Do not give this medicine to a child under the age of 18 years. It is not known if ZEPATIER is safe or effective in children under 18 years old.

How to use ZEPATIER

Use ZEPATIER exactly as your doctor tells you to take it.

How much to take and when to take it

Take one tablet at the same time every day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take it

ZEPATIER comes in a foil blister pack of individually packaged tablets. Keep the tablets in this pack

until you are ready to take your medicine.

You can take ZEPATIER with or without food.

How long to take ZEPATIER

Continue taking your medicine for as long as your doctor tells you. Do not stop taking ZEPATIER without first talking to your doctor.

If you forget to take ZEPATIER

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 have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre for advice (telephone number for Australia: 13 11 26).

Keep the telephone number handy.

While you are taking ZEPATIER

Things you must do

- Use ZEPATIER exactly as your doctor has prescribed.
- Tell all doctors, dentists and pharmacists who are treating

you that you are using ZEPATIER.

- **Keep all your doctor's appointments so that your progress can be checked.**

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

- **Stop using ZEPATIER in combination with ribavirin if you become pregnant and immediately tell your doctor. If your partner becomes pregnant while you are using ZEPATIER in combination with ribavirin, ask your partner to tell her doctor immediately.**

Things you must not do

- Do not use it to treat any other complaints.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not let yourself run out of medicine over weekends or holiday periods.

Things to be careful of

If your doctor has prescribed this medicine together with another medicine called ribavirin, please read the Consumer Medicine Information for ribavirin for other things to be careful of when these medicines are used in combination.

Side effects

All medicines have side effects. Sometimes they are serious, most of the time they are not.

Ask your doctor or pharmacist any questions you may have.

Check with your doctor immediately:

Tell your doctor immediately if you start having any of the following symptoms, or if they get

worse during treatment with ZEPATIER:

- loss of appetite
- nausea (feeling sick) and vomiting
- feeling tired or weak
- yellowing of your skin or eyes
- colour changes in your stool

Tell your doctor immediately if you have an allergic reaction.

Symptoms of an allergic reaction may include:

- hives, itching or skin rash
- swelling of the face, lips or tongue. This may lead to difficulty in swallowing.
- shortness of breath, wheezing, difficulty in breathing or a tight feeling in your chest.

Hepatitis B virus reactivation: Before starting treatment with ZEPATIER, your healthcare provider will do blood tests to check for hepatitis B virus infection.

If you have ever had hepatitis B virus infection, the hepatitis B virus could become active again during or after treatment of hepatitis C virus infection with ZEPATIER.

Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems including liver failure and death.

Your healthcare provider will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop taking ZEPATIER.

Common side effects:

Tell your doctor if you notice any of the following and they worry you while taking ZEPATIER:

- headache
- feeling tired
- nausea (feeling sick)

These are common side effects of ZEPATIER.

The following are common side effects of ZEPATIER in

combination with ribavirin. Tell your doctor if you notice any of the following and they worry you:

- headache
- feeling tired or weak
- nausea (feeling sick) or vomiting
- itching
- muscle aches
- trouble sleeping
- shortness of breath
- indigestion
- signs of a low red blood cell count (tiredness, headaches, being short of breath when exercising, dizziness and looking pale)

Other side effects not listed above may also occur in some patients. If you notice any other side effects, check with your doctor.

Check with your doctor as soon as possible if you have any problems while using ZEPATIER, even if you do not think the problems are connected with the medicines.

Do not be alarmed by the list of possible side effects. You may not experience any of them.

Please read the Consumer Medicine Information for ribavirin for other things to be careful of when ZEPATIER is used in combination with ribavirin.

After using ZEPATIER

Storage

Store below 30°C.

Keep ZEPATIER in its original blister pack until you are ready to take it. Do not take the tablets out of the original blister pack to store in another container such as a pill box. This is important because the tablets are sensitive to moisture. The pack is designed to protect them.

Do not store the tablets in the bathroom or near a sink. Heat and

dampness can destroy some medicines.

Keep all medicines where children cannot reach. A locked cupboard at least 1.5 metres above the ground is a good place to store medicines.

Disposal

Return any unused medicine to your pharmacist.

Product description

What it looks like

ZEPATIER (elbasvir and grazoprevir) is a beige film-coated tablet with '770' imprinted on one side. Each tablet contains 50mg of elbasvir and 100mg of grazoprevir.

The tablets are packaged into a carton containing two cardboard wallets; each cardboard wallet contains 14 tablets within aluminium blisters. Each carton contains a total of 28 tablets.

Ingredients

Each ZEPATIER tablet contains:

- elbasvir 50mg
- grazoprevir 100mg
- lactose monohydrate 72mg
- sodium lauryl sulphate
- copovidone
- mannitol
- croscarmellose sodium
- sodium chloride
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- tocopherol
- microcrystalline cellulose

The tablet film coating contains:

- lactose monohydrate
- hypromellose
- titanium dioxide
- glycerol triacetate
- iron oxide red

- iron oxide yellow
- ferrousferrous oxide
- Carnauba wax

Supplier

Merck Sharp & Dohme (Australia) Pty Limited

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Australia

Australian Registration Number

AUST R 259928

Date of Preparation

August 2020

RCN000011167-AU