

Package leaflet: Information for the user

ZEPATIER® 50 mg/100 mg film-coated tablets elbasvir/grazoprevir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take ZEPATIER
3. How to take ZEPATIER
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1. What ZEPATIER is and what it is used for

What ZEPATIER is

ZEPATIER is an antiviral medicine that contains the active substances elbasvir and grazoprevir.

What ZEPATIER is used for

ZEPATIER is used to treat long-term hepatitis C infection in adults and children aged 12 years and older who weigh at least 30 kilograms.

How ZEPATIER works

Hepatitis C is a virus that infects the liver. The active substances in the medicine work together by blocking two different proteins that the hepatitis C virus needs to grow and reproduce. This allows the infection to be permanently removed from the body.

ZEPATIER is sometimes taken with another medicine, ribavirin.

It is very important that you also read the leaflets for the other medicines that you will be taking with ZEPATIER. If you have any questions about your medicines, please ask your doctor or pharmacist.

2. What you need to know before you take ZEPATIER

Do not take ZEPATIER if:

- you are allergic to elbasvir, grazoprevir or any of the other ingredients of this medicine (listed in section 6)
- you have certain moderate or severe liver problems
- you are taking any of the following medicines:
 - rifampicin, usually given for tuberculosis
 - HIV protease inhibitors such as atazanavir, darunavir, lopinavir, saquinavir, or tipranavir
 - efavirenz or etravirine for HIV
 - elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate or elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide for HIV

- ciclosporin to stop organ transplant rejection or to treat serious inflammatory illnesses of eyes, kidney, joints or skin
- bosentan for pulmonary arterial hypertension
- carbamazepine or phenytoin, mainly used for epilepsy and seizures
- modafinil to help people who cannot stay awake
- St. John's wort (*Hypericum perforatum*, a herbal medicine) for depression or other problems.

If you are taking ZEPATIER with ribavirin, please make sure that you read the "Do not take" section of the ribavirin package leaflet. If you are unsure of any information in the package leaflet, please contact your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking ZEPATIER if you:

- have a current or previous infection with the hepatitis B virus, since your doctor may want to monitor you more closely
- have ever taken any medicine for hepatitis C
- have any liver problems other than hepatitis C
- have had a liver transplant
- have diabetes. You may need closer monitoring of your blood glucose levels and/or adjustment of your diabetes medication after starting ZEPATIER. Some diabetic patients have experienced low sugar levels in the blood (hypoglycaemia) after starting treatment with medicines like ZEPATIER
- have any other medical conditions.

Blood tests

Your doctor will test your blood before, during and after your treatment with ZEPATIER. This is so your doctor can:

- decide if you should take ZEPATIER and for how long
- decide what other medicines you should take with ZEPATIER and for how long
- check for side effects
- check if your treatment has worked and you are free of hepatitis C
- check how your liver is working - tell your doctor straight away if you have any of the following signs of liver problems: loss of appetite; feeling or being sick; feeling tired or weak; yellowing of your skin or eyes; colour changes in your stool. Your doctor may want to test your blood to check how your liver is working if you develop any of these symptoms.

Children

ZEPATIER is not for use in children younger than 12 years of age.

Other medicines and ZEPATIER

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and medicines obtained without a prescription. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

There are some medicines you **must not take** with ZEPATIER. See list under "Do not take ZEPATIER if you are taking any of the following medicines."

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

- oral ketoconazole for fungal infections
- tacrolimus to prevent organ transplant rejection
- dabigatran to prevent blood clots
- rosuvastatin, atorvastatin, fluvastatin, simvastatin, or lovastatin, for lowering blood cholesterol
- sunitinib to treat certain cancers

- warfarin and other similar medicines called vitamin K antagonists used to thin the blood. Your doctor may need to increase the frequency of your blood tests to check how well your blood can clot.

Your liver function may improve with treatment of hepatitis C and therefore may affect other medications that are handled by the liver. Your doctor may need to closely monitor these other medicines you are taking and make adjustments during ZEPATIER therapy.

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.

Pregnancy and contraception

The effects of ZEPATIER in pregnancy are not known. If you are pregnant, think you might be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

ZEPATIER with ribavirin

- You must not become pregnant if you are taking ZEPATIER with ribavirin. Ribavirin can be very damaging to an unborn baby. This means you and your partner must take special precautions in sexual activity if there is any chance you or your partner could become pregnant.
- You or your partner must use an effective method of contraception during treatment with ZEPATIER with ribavirin and for some time afterwards. Talk to your doctor about different contraception methods that are suitable for you.
- If you or your partner becomes pregnant while taking ZEPATIER with ribavirin or in the months that follow, tell your doctor straight away.
- It is very important that you read the information concerning pregnancy and contraception in the ribavirin package leaflet very carefully. It is important that both men and women read the information.

Breast-feeding

Talk to your doctor before taking ZEPATIER if you are breast-feeding. It is not known whether the two medicines in ZEPATIER pass into human breast milk.

If you are taking ZEPATIER with ribavirin, make sure that you also read the Pregnancy and Breast-feeding sections of the package leaflet for this other medicine.

Driving and using machines

Do not drive or operate machines if you feel tired after taking your medicine.

ZEPATIER contains lactose

ZEPATIER contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

ZEPATIER contains sodium

This medicine contains 69.85 mg sodium (main component of cooking / table salt) in each tablet. This is equivalent to 3.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take ZEPATIER

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Talk to your doctor or pharmacist before taking ZEPATIER if you have ever taken any medicines for hepatitis C or if you have any other medical condition.

How much to take

The recommended dose is **one tablet once a day** with or without food. Your doctor will tell you how many weeks you should take ZEPATIER for.

Swallow the tablet whole with or without food. Do not chew, crush or split the tablet. Tell your doctor or pharmacist if you have problems swallowing tablets.

If you take more ZEPATIER than you should

If you take more ZEPATIER than you should, talk to a doctor straight away. Take the medicine pack with you so that you can show the doctor what you have taken.

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 your next dose at your usual time.
- Do not take a double dose (two doses together) to make up for a forgotten dose.

Do not stop taking ZEPATIER

Do not stop taking this medicine unless your doctor tells you to. It is very important that you complete the full course of treatment. This will give the medicine the best chance to treat your hepatitis C infection.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Tell your doctor or pharmacist if you notice any of the following side effects.

Very common: may affect more than 1 in 10 people

- feeling very tired (fatigue)
- headache

Common: may affect up to 1 in 10 people

- feeling sick (nausea)
- feeling weak or lack of energy (asthenia)
- itching
- diarrhoea
- trouble sleeping (insomnia)
- joint pain or painful, swollen joints
- constipation
- feeling dizzy
- loss of appetite
- feeling irritable
- muscle aches
- stomach pain
- unusual hair loss or thinning
- feeling nervous (anxiety)
- depression
- dry mouth

- being sick (vomiting)

Uncommon: may affect up to 1 in 100 people

- abnormalities in laboratory tests of liver function

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ZEPATIER

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the carton and blister packaging after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original package until use to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What ZEPATIER contains

- **The active substances are:** elbasvir and grazoprevir. Each film-coated tablet contains 50 mg elbasvir and 100 mg grazoprevir.
- **The other ingredients are:**

Tablet core:

Sodium laurilsulfate, vitamin E polyethylene glycol succinate, copovidone, hypromellose, microcrystalline cellulose, mannitol (E421), lactose monohydrate, croscarmellose sodium, sodium chloride, colloidal anhydrous silica, magnesium stearate.

Film-coating:

Lactose monohydrate, hypromellose, titanium dioxide, triacetin, iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172), carnauba wax.

What ZEPATIER looks like and contents of the pack

The film-coated tablets are beige, oval, debossed with "770" on one side and plain on the other. The tablet is 21 mm long and 10 mm wide.

The tablets are packaged into a carton containing two cardboard cards, each cardboard card containing two 7-count aluminium blisters. Each carton contains a total of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, EC2M 6UR, United Kingdom.

Manufacturer: Organon Heist bv, Industriepark 30, 2220 Heist-op-den-Berg, Belgium.

For any information about this medicine, please contact:

Merck Sharp & Dohme (UK) Limited
Tel: +44 (0) 208 154 8000
Email: medicalinformationuk@msd.com

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