

Package leaflet: Information for the user

Glecaprevir/Pibrentasvir 100 mg/40 mg film-coated tablets

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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1. What Glecaprevir/Pibrentasvir is and what it is used for

Glecaprevir/Pibrentasvir is an antiviral medicine used to treat adults and children 3 years and older with long-term ('chronic') hepatitis C. This is an infectious disease that affects the liver, caused by the hepatitis C virus. Glecaprevir/Pibrentasvir contains the active substances glecaprevir and pibrentasvir.

Glecaprevir/Pibrentasvir works by stopping the hepatitis C virus from multiplying and infecting new cells. This allows the infection to be eliminated from the body.

2. What you need to know before you take Glecaprevir/Pibrentasvir

Do not take Glecaprevir/Pibrentasvir if:

- you are allergic to glecaprevir, pibrentasvir or any of the other ingredients of this medicine (listed in section 6).
- you have severe liver problems other than from hepatitis C.
- you are taking the following medicines:
 - atazanavir (for HIV infection)
 - atorvastatin or simvastatin (to lower blood cholesterol)
 - carbamazepine, phenobarbital, phenytoin, primidone (normally used for epilepsy)
 - dabigatran etexilate (to prevent blood clots)
 - ethinyl oestradiol-containing medicines (such as contraception medicines, including vaginal rings, transdermal patches, and tablets)
 - rifampicin (for infections)
 - St. John's wort (*Hypericum perforatum*) (herbal remedy used for mild depression).

Do not take Glecaprevir/Pibrentasvir if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Glecaprevir/Pibrentasvir .

Warnings and precautions

Talk to your doctor if you have the following because your doctor may want to check you more closely:

- liver problems other than hepatitis C

- current or previous infection with the hepatitis B virus
- diabetes. You may need closer monitoring of your blood glucose levels and/or adjustment of your diabetes treatment after starting Glecaprevir/Pibrentasvir . Some diabetic patients have experienced low sugar levels in the blood (hypoglycaemia) after starting treatment with medicines like Glecaprevir/Pibrentasvir .

Blood tests

Your doctor will test your blood before, during and after your treatment with Glecaprevir/Pibrentasvir . This is so that your doctor can decide if:

- you should take Glecaprevir/Pibrentasvir and for how long
- your treatment has worked and you are free of the hepatitis C virus.

Children

Do not give this medicine to children under 3 years of age or weighing less than 12 kg. The use of Glecaprevir/Pibrentasvir in children under 3 years of age or weighing less than 12 kg has not yet been studied.

Other medicines and Glecaprevir/Pibrentasvir

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor or pharmacist before taking Glecaprevir/Pibrentasvir , if you are taking any of the medicines in the table below. The doctor may need to change your dose of these medicines.

Medicines you must tell your doctor about before taking Glecaprevir/Pibrentasvir	
Medicine	Purpose of the medicine
ciclosporin, tacrolimus	to suppress the immune system
darunavir, efavirenz, lopinavir, ritonavir	for HIV infection
digoxin	for heart problems
fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin	to lower blood cholesterol
warfarin and other similar medicines*	to prevent blood clots

*Your doctor may need to increase the frequency of your blood tests to check how well your blood can clot.

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

Pregnancy and contraception

The effects of Glecaprevir/Pibrentasvir during pregnancy are not known. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine, as the use of Glecaprevir/Pibrentasvir in pregnancy is not recommended. Contraceptive medicines that contain ethinylestradiol must not be used in combination with Glecaprevir/Pibrentasvir .

Breast-feeding

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

Driving and using machines

Glecaprevir/Pibrentasvir should not affect your ability to drive or use any tools or machines.

Glecaprevir/Pibrentasvir contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Glecaprevir/Pibrentasvir contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Glecaprevir/Pibrentasvir

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how long you need to take Glecaprevir/Pibrentasvir for. Glecaprevir/Pibrentasvir tablets are intended for adults, children 12 years and older, or children weighing 45 kg or more. Glecaprevir/Pibrentasvir coated granules are intended for children aged 3 years to less than 12 years and weighing 12 kg to less than 45 kg.

How much to take

The recommended dose for adults, children aged 12 years and older, or children weighing at least 45 kg is three tablets of Glecaprevir/Pibrentasvir 100 mg/40 mg taken together, once a day. Three tablets in one blister is the daily dose.

How to take

- Take the tablets with food.
- Swallow the tablets whole.
- Do not chew, crush or break the tablets as it may affect the amount of Glecaprevir/Pibrentasvir in your blood.

If you are sick (vomit) after taking Glecaprevir/Pibrentasvir it may affect the amount of Glecaprevir/Pibrentasvir in your blood. This may make Glecaprevir/Pibrentasvir work less well.

- If you vomit **less than 3 hours** after taking Glecaprevir/Pibrentasvir, take another dose.
- If you vomit **more than 3 hours** after taking Glecaprevir/Pibrentasvir, you do not need to take another dose until your next scheduled dose.

If you take more Glecaprevir/Pibrentasvir than you should

If you accidentally take more than the recommended dose, contact your doctor or go to the nearest hospital straight away. Take the medicine pack with you so that you can show the doctor what you have taken.

If you forget to take Glecaprevir/Pibrentasvir

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 last taken Glecaprevir/Pibrentasvir:

- If you notice **within 18 hours** of the time you usually take Glecaprevir/Pibrentasvir, take the dose as soon as possible. Then take the next dose at your usual time.
- If you notice **18 hours or more** after the time you usually take Glecaprevir/Pibrentasvir, wait and take the next dose at your usual time. Do not take a double dose to make up for a forgotten tablet.

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.

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)
- diarrhoea
- feeling weak or lack of energy (asthenia)
- increase in a laboratory test of liver function (bilirubin)

Uncommon: may affect up to 1 in 100 people

- swelling of the face, lips, tongue, throat, abdomen, arms or legs

Not known: cannot be estimated from the available data

- itching

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 national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Glecaprevir/Pibrentasvir

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

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

This medicine does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What Glecaprevir/Pibrentasvir contains

- The active substances are glecaprevir and pibrentasvir. Each tablet contains 100 mg of glecaprevir and 40 mg of pibrentasvir.
- The other ingredients are:
 - Tablet core: copovidone (Type K 28), vitamin E polyethylene glycol succinate, silica, anhydrous colloidal, propylene glycol monocaprylate (type II), croscarmellose sodium, sodium stearyl fumarate.

- Tablet film-coating: hypromellose (E464), lactose monohydrate, titanium dioxide, macrogol 3350, iron oxide red (E172).

Glecaprevir/Pibrentasvir contains lactose and sodium. See section 2.

What Glecaprevir/Pibrentasvir looks like and contents of the pack

Glecaprevir/Pibrentasvir tablets are pink, oblong, curved on both sides (biconvex), film-coated tablets (tablets) with dimensions of 18.8 mm x 10.0 mm and debossed on one side with ‘NXT’.

Glecaprevir/Pibrentasvir tablets are packed into foil blisters, each containing 3 tablets.

Glecaprevir/Pibrentasvir is available in a pack of 84 tablets as 4 cartons, each containing 21 film-coated tablets.

Marketing Authorisation Holder

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