

## Early Access to Medicines Scheme – Treatment protocol – Information for patients

### Introduction

The aim of the Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed medicines (medicines that do not have a marketing authorisation) to UK patients that have a high unmet clinical need. The medicines included in the scheme are those that are intended to treat, diagnose or prevent seriously debilitating or life threatening conditions where there are no adequate treatment options. More information about the scheme can be found here:

<http://www.mhra.gov.uk/Howweregulate/Innovation/EarlyaccesstomedicinesschemeEAMS/index.htm>

The information below is intended for you, the patient, and is provided by the pharmaceutical company that manufactures the medicine. This medicine does not yet have a drug licence (also called a marketing authorisation). More information about medicines licensing can be found here:

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/MymedicineFromlaboratorytopharmacyshelf/Licensingmarketingauthorisation/index.htm>

This medicine can be prescribed for individual patients to meet specific needs provided they are given sufficient information about the medicine to make an informed decision. Informed consent should be obtained from you prior to treatment.

This information is provided to help you decide with your doctor on whether to use the medicine and helps explain how to use the medicine in accordance with the pharmaceutical company's instructions for safe and proper use. Whilst you are using this medicine, data will be collected on the use and safety profile of the medicine, to ensure that the benefits of taking the medicine outweigh any potential risks.

**Information for the patient:**

**Information for the patient**

**glecaprevir/pibrentasvir 100 mg/40 mg film-coated tablets**  
glecaprevir/pibrentasvir

**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**

1. What glecaprevir/pibrentasvir is and what it is used for
2. What you need to know before you take glecaprevir/pibrentasvir
3. How to take glecaprevir/pibrentasvir
4. Possible side effects
5. How to store glecaprevir/pibrentasvir
6. Contents of the pack and other information

**1. What glecaprevir/pibrentasvir is and what it is used for**

Glecaprevir/Pibrentasvir is an antiviral medicine used to treat adults with long-term hepatitis C, an infectious disease that affects the liver, caused by the hepatitis C virus.

It is for the treatment of

- patients with hepatitis C (genotypes 1, 4, 5 and 6) who have compensated cirrhosis and have been previously treated with NS5A inhibitors
- patients with hepatitis C (genotypes 2, 3, 5 or 6) who have chronic kidney disease (stage 4 and 5)
- patients with hepatitis C (genotypes 3) with compensated cirrhosis

Glecaprevir/pibrentasvir works by stopping the hepatitis C virus from multiplying and infecting new cells. This allows the infection to be permanently 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 of this leaflet).
- you have liver problems other than from hepatitis C.
- you are taking the medicines atazanavir (for HIV infection) or rifampicin (for infections).
- you are pregnant or breastfeeding

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
- hepatitis B

### 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 and adolescents

Do not give this medicine to children and adolescents under 18 years of age. The use of glecaprevir/pibrentasvir in children and adolescents 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. This includes herbal medicines and medicines obtained without a prescription.

**Do not take glecaprevir/pibrentasvir** and tell your doctor or pharmacist if you are taking any of the following medicines:

- atazanavir - for HIV infection
- rifampicin - for infections.

**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.

<b>Medicines you must tell your doctor about before taking glecaprevir/pibrentasvir</b>	
<b>Medicine</b>	<b>Purpose of the medicine</b>
atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin	to lower blood cholesterol
carbamazepine	normally used for epilepsy
ciclosporin	to suppress the immune system
dabigatran	to thin the blood
darunavir, efavirenz, lopinavir, ritonavir	for HIV infection
digoxin	for heart problems or high blood pressure
ethinyloestradiol	for contraception or hormone replacement therapy
St John's wort ( <i>Hypericum perforatum</i> )	for mild depression
vitamin K antagonists such as warfarin or other similar medicines*	to thin the blood

\*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.

### 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, talk to your doctor before taking this medicine.

### **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.

#### **How much to take**

The recommended dose is three tablets taken together, once a day.

#### **How to take**

- Take the tablets with food.
- Swallow the tablets whole.
- Do not chew, crush or break the tablets.

#### **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. Keep the medicine pack with you so you can easily describe 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 (two doses close together).

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)

#### **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 (website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)). By reporting side effects you can help provide more information on the safety of this medicine.

## 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 bottle label.

Store this medicine below 30° C in the original package to protect from moisture.

Keep the bottle tightly closed.

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, colloidal anhydrous, propylene glycol monacrylate (type II), croscarmellose sodium, sodium stearyl fumarate.
  - Tablet film-coating: hypromellose (E464), lactose monohydrate, titanium dioxide, macrogol 3350, iron oxide red (E172).

### What glecaprevir/pibrentasvir looks like and contents of the pack

Glecaprevir/pibrentasvir tablets are pink, oblong, curved on both sides (biconvex), film-coated tablets with dimensions of 18.8 mm x 10.0 mm and debossed on one side with '2nd'.

Glecaprevir/pibrentasvir tablets are packed in a bottle containing 30 film-coated tablets.

### Scientific Opinion Holder

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### Manufacturer

AbbVie Deutschland GmbH & Co. KG  
Knollstrasse  
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**Additional information:**

*[The Applicant should insert here any additional relevant information if required e.g. patient alert card, educational material, text to explain how the patient should obtain relevant material ]*

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