

Package leaflet: Information for the user

Glecaprevir/Pibrentasvir 50 mg/20 mg coated granules in sachet

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to their 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 your child takes Glecaprevir/Pibrentasvir
3. How to take Glecaprevir/Pibrentasvir
4. Possible side effects
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1. What Glecaprevir/Pibrentasvir is and what it is used for

Glecaprevir/Pibrentasvir is an antiviral medicine used to treat children aged 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 your child takes Glecaprevir/Pibrentasvir

Do not give Glecaprevir/Pibrentasvir if:

- your child is allergic to glecaprevir, pibrentasvir or any of the other ingredients of this medicine (listed in section 6 of this leaflet).
- your child has severe liver problems other than from hepatitis C.
- your child is 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 and tablets)
 - rifampicin (for infections)
 - St. John's wort (*Hypericum perforatum*), (herbal remedy used for mild depression).

Do not give Glecaprevir/Pibrentasvir to your child if any of the above apply. If you are not sure, talk to your child's doctor or pharmacist before giving Glecaprevir/Pibrentasvir.

Warnings and precautions

Talk to your child's doctor if they have the following because the doctor may want to check your child more closely:

- liver problems other than hepatitis C
- current or previous infection with the hepatitis B virus
- diabetes. Your child may need closer monitoring of their blood glucose levels and/or adjustment of diabetes medicine 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 child's doctor will test their blood before, during and after treatment with Glecaprevir/Pibrentasvir. This is so that the doctor can decide if:

- Your child should take Glecaprevir/Pibrentasvir and for how long
- The treatment has worked and your child is free of the hepatitis C virus.

Children under 3 years old

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

Other medicines and Glecaprevir/Pibrentasvir

Tell your child's doctor or pharmacist if they are taking, have recently taken or might take any other medicines.

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

Medicines you must tell your child's doctor about before giving 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 child's doctor may need to increase the frequency of blood tests to check how well your child's blood can clot.

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

Glecaprevir/Pibrentasvir contains lactose

If you have been told by your doctor that your child has an intolerance to some sugars, talk to your doctor before giving this medicine.

Glecaprevir/Pibrentasvir contains propylene glycol

Glecaprevir/Pibrentasvir contains 4mg propylene glycol in each sachet.

Glecaprevir/Pibrentasvir contains sodium

Glecaprevir/Pibrentasvir contains less than 1 mmol sodium (23mg) in each sachet, that is to say is essentially 'sodium free'.

3. How to take Glecaprevir/Pibrentasvir

Always give this medicine exactly as your child's doctor or pharmacist has told you. Check with your child's doctor or pharmacist if you are not sure. Glecaprevir/Pibrentasvir coated granules are intended

for children aged 3 years to less than 12 years and weighing 12 kg to less than 45kg. Glecaprevir/Pibrentasvir tablets are intended for adults, children 12 years and older, or children weighing 45kg or more.

Your child's doctor will tell you how long your child needs to take Glecaprevir/Pibrentasvir for.

How much to take

The recommended dose for children 3 to less than 12 years old is based on their body weight as shown in the table below.

Weight of child (kg)	Number of sachets once daily
From 12 to less than 20 kg	3 sachets
From 20 to less than 30 kg	4 sachets
From 30 to less than 45 kg	5 sachets

For children weighing 45kg or more, talk to your child's doctor about giving Glecaprevir/Pibrentasvir tablets.

How to take Glecaprevir/Pibrentasvir

- Give Glecaprevir/Pibrentasvir once a day just before or after a snack or meal.
- Mix all the granules in the sachet with a small amount of recommended food and swallow (see Instructions for Use for list of recommended food).
- Do not give Glecaprevir/Pibrentasvir granules through a feeding tube.

If your child is sick (vomits) after taking Glecaprevir/Pibrentasvir it may affect the amount of Glecaprevir/Pibrentasvir in their blood. This may make Glecaprevir/Pibrentasvir work less well.

- If they vomit less than 3 hours after taking Glecaprevir/Pibrentasvir, give another dose.
- If they vomit more than 3 hours after taking Glecaprevir/Pibrentasvir, you do not need to give another dose until the next dose is due.

If they take more Glecaprevir/Pibrentasvir than they should

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

If you forget to give Glecaprevir/Pibrentasvir

It is important not to miss a dose of this medicine.

If your child does miss a dose, work out how long it is since they should have last taken Glecaprevir/Pibrentasvir:

- If you notice within 18 hours of the time your child usually takes Glecaprevir/Pibrentasvir, give the dose as soon as possible. Then give the next dose at the usual time.
- If you notice 18 hours or more after the time your child usually takes Glecaprevir/Pibrentasvir, wait and give the next dose at the usual time. Do not give a double dose (two doses too close together).

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your child's 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)

Uncommon: may affect up to 1 in 100 people

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

Not known: frequency cannot be estimated from the available data

- itching

Reporting of side effects

If your child gets any side effects, talk to your child's 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 sachet after 'EXP'.

This medicine does not require any special storage.

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 sachet contains 50 mg of glecaprevir and 20 mg of pibrentasvir.
- The other ingredients are:
- Copovidone, tocofersolan, propylene glycol monocaprylate, colloidal silicon dioxide, croscarmellose sodium (in the glecaprevir granules only), sodium stearyl fumarate, hypromellose (E464), lactose monohydrate, titanium dioxide, macrogol, iron oxide red (E172), iron oxide yellow (E172)

Glecaprevir/Pibrentasvir

What Glecaprevir/Pibrentasvir looks like and contents of the pack

Glecaprevir/Pibrentasvir coated granules are supplied in polyester/aluminium/polyethylene film sachets in cartons. Each carton contains 28 sachets. Each sachet contains pink and yellow granules.

Marketing Authorisation Holder

AbbVie Ltd
Maidenhead
SL6 4UB
UK

Manufacturer

AbbVie S.r.l.
 S.R. 148 Pontina km 52 SNC
 04011 Campoverde di Aprilia (LT)
 Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

AbbVie Ltd
 Tel: +44 (0)1628 561090

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To listen to or request a copy of this leaflet in Braille, large print or audio, please contact the local representative of the Marketing Authorisation Holder.

7. Instructions for use

Please read all of section 7 before using Glecaprevir/Pibrentasvir granules in sachets.

Step 1. Get the number of sachets as advised by your child's doctor

Weight of child (kg)	Number of sachets once daily	Food Amount (approximate)
From 12 to less than 20 kg	3 sachets	About 1-2 teaspoons (5-10 mL) of recommended food listed in step 2
From 20 to less than 30 kg	4 sachets	
From 30 to less than 45 kg	5 sachets	

For children weighing 45 kg or more, talk to your child's doctor about giving Glecaprevir/Pibrentasvir tablets.

Do not give more than 5 sachets.

Step 2. Choose suitable food to mix with Glecaprevir/Pibrentasvir granules

Suitable food should stick to the spoon. It must be soft, low in water content and can be swallowed without chewing.

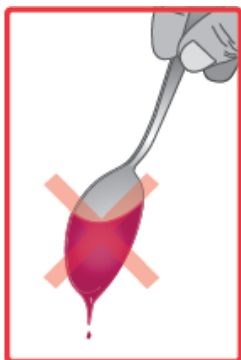


Example of recommended foods:

- ✓ Greek yogurt
- ✓ Cream/soft cheese
- ✓ Peanut butter
- ✓ Chocolate hazelnut spread
- ✓ Thick jam
- ✓ Other food that sticks to the spoon

Note: in addition to the food used to mix the granules, Glecaprevir/Pibrentasvir should also be taken at the same time or straight after a meal or snack. The food used to mix the granules does not replace the meal or snack to take with Glecaprevir/Pibrentasvir.

Do not use food if it drips off a spoon as the medicine may dissolve quickly, taste bitter, and become less effective. **Do not** use food that your child is allergic to.



Example of foods **not** to use:

- ✗ Liquids or watery food
- ✗ Apple sauce
- ✗ Food or liquid that is heated or frozen
- ✗ Bread or other food that requires chewing
- ✗ Non-Greek yogurt
- ✗ Baby food
- ✗ Food that drips off the spoon

For more information about suitable foods, contact your child's doctor or pharmacist.

Step 3. Gather materials



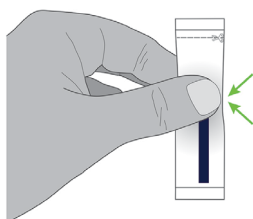
Place the following on a clean surface:

- Box with sachets in it
- Soft food
- Bowl to use for mixing
- Teaspoon
- Scissors



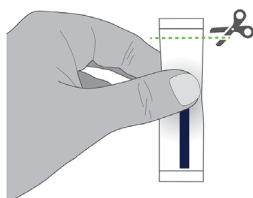
Step 4. Measure food

- Place a small amount (1-2 teaspoons or 5-10 mL) of soft food into a bowl.
- The granules inside the sachets are very small, so placing food in the bowl first will help contain them.



Step 5. Prepare sachet

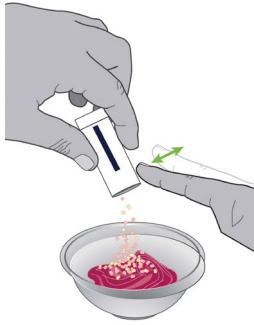
- Look for the dotted line on the sachet to find the top end.
- Hold the sachet upright and tap the top of the sachet. Keep tapping until all the granules inside fall to the bottom.
- Feel top area of sachet thoroughly to make sure all granules are at the bottom.



Step 6. Cut top of sachet

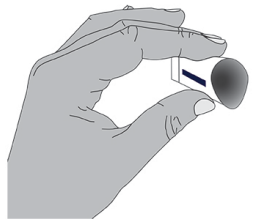
- Pinch the sachet in the centre, above the granules inside.
- Use scissors to cut the top of the sachet completely off.

Be Careful: Granules are very small and can fall out easily.



Step 7. Pour sachet

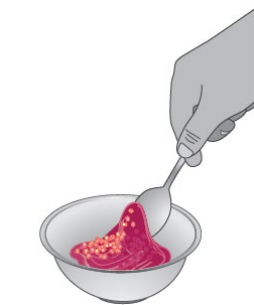
- Make sure the sachet is fully open.
- Carefully pour all granules (pink and yellow) out of the sachet into the bowl of food.
- Tap sachet to get all the granules out.
- Repeat for each sachet for your child's daily dose.



Step 8. Check sachet

Look inside each sachet to make sure there are no granules left inside.

Do not leave any granules behind as the medicine will not work as well if the full dose is not taken.



Step 9. Mix

- Use the teaspoon to gently stir the granules into the food.
- **Do not** crush the granules. If the granules are crushed, they will taste bitter.
- **Do not** store the mixture, give it to your child immediately.

If not given within 5 minutes, the mixture may taste bitter.

If not given within 15 minutes, the medicine may be less effective. Throw away and start again.



Step 10. Give the medicine

- Scoop a small amount of mixture onto the teaspoon.
- Make sure your child swallows the mixture without chewing.
- Repeat until your child has taken all the mixture.
- If any granules are left, add more food and mix. Then finish the dose.
- Make sure your child takes the full dose of the medicine.

⚠ If your child misses a dose, see Section 3 “How to take Glecaprevir/Pibrentasvir” for further information.



Step 11. Confirm dose for tomorrow

Check to make sure there are enough sachets for your child's next dose of Glecaprevir/Pibrentasvir.

For replacement sachets or to refill your prescription contact your child's doctor or pharmacist.