

<b>MAVYRET® (MAV-ih-reht)</b> (glecaprevir and pibrentasvir) tablets	<b>Patient Information</b>  <b>MAVYRET® (MAV-ih-reht)</b> (glecaprevir and pibrentasvir) oral pellets
<p><b>What is the most important information I should know about MAVYRET?</b>  <b>MAVYRET can cause serious side effects, including:</b>  <b>Hepatitis B virus reactivation.</b> Before starting treatment with MAVYRET, 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 for hepatitis C virus with MAVYRET. Hepatitis B virus that becomes 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 MAVYRET.  <b>For more information about side effects, see the section “What are the possible side effects of MAVYRET?”</b></p>	
<p><b>What is MAVYRET?</b>          MAVYRET is a prescription medicine used to treat adults and children 3 years of age and older with:</p> <ul style="list-style-type: none"> <li>• acute (recently infected) or chronic (lasting a long time) hepatitis C virus (HCV) genotypes 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis.</li> <li>• HCV genotype 1 infection who have been previously treated with a regimen that contained an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.</li> </ul> <p>MAVYRET contains the 2 medicines: glecaprevir and pibrentasvir.          It is not known if MAVYRET is safe and effective in children under 3 years of age.</p>	
<p><b>Do not take MAVYRET if you:</b></p> <ul style="list-style-type: none"> <li>• have certain liver problems</li> <li>• also take any of the following medicines:             <ul style="list-style-type: none"> <li>◦ atazanavir</li> <li>◦ rifampin</li> </ul> </li> </ul>	
<p><b>Before taking MAVYRET, tell your healthcare provider about all of your medical conditions, including if you:</b></p> <ul style="list-style-type: none"> <li>• have had hepatitis B virus infection</li> <li>• have liver problems other than hepatitis C virus infection</li> <li>• have HIV-1 infection</li> <li>• have had a liver or a kidney transplant</li> <li>• are pregnant or plan to become pregnant. It is not known if MAVYRET will harm your unborn baby.</li> <li>• are breastfeeding or plan to breastfeed. It is not known if MAVYRET passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with MAVYRET.</li> </ul> <p><b>Tell your healthcare provider about all the medicines you take</b>, including prescription and over-the-counter medicines, vitamins, and herbal supplements.          MAVYRET and other medicines may affect each other. This can cause you to have too much or not enough MAVYRET or other medicines in your body. This may affect the way MAVYRET or your other medicines work or may cause side effects.</p> <p><b>Keep a list of your medicines to show your healthcare provider and pharmacist.</b></p> <ul style="list-style-type: none"> <li>• You can ask your healthcare provider or pharmacist for a list of medicines that interact with MAVYRET.</li> <li>• <b>Do not start taking a new medicine without telling your healthcare provider.</b> Your healthcare provider can tell you if it is safe to take MAVYRET with other medicines.</li> </ul>	
<p><b>How should I take MAVYRET?</b></p> <ul style="list-style-type: none"> <li>• Take MAVYRET exactly as your healthcare provider tells you to take it. Do not change your dose unless your healthcare provider tells you to.</li> <li>• Do not stop taking MAVYRET without first talking with your healthcare provider.</li> <li>• Do not miss or skip doses of MAVYRET during treatment.</li> <li>• Take MAVYRET with food.</li> <li>• For adults, adolescents 12 years and older, or children weighing at least 99 pounds (45 kg), the usual dose of MAVYRET is 3 tablets at the same time each day.</li> </ul>	

- For children 3 years to less than 12 years of age and weighing less than 99 pounds (45 kg), your child's healthcare provider will prescribe the right dose of MAVYRET oral pellets based on your child's body weight.
  - If your child's healthcare provider prescribes MAVYRET oral pellets for your child, see **"How should I give MAVYRET oral pellets to my child?"**
- If you miss a dose of MAVYRET and it is:
  - Less than 18 hours from the time you usually take MAVYRET, take the missed dose with food as soon as possible. Then take your next dose at your usual time.
  - More than 18 hours from the time you usually take MAVYRET, do not take the missed dose. Take your next dose at your usual time with food.
- If you take too much MAVYRET, call your healthcare provider or go to the nearest hospital emergency room right away.

#### **How should I give MAVYRET oral pellets to my child?**

**See the detailed Instructions for Use for information about how to give or take a dose of MAVYRET oral pellets.**

- Give MAVYRET oral pellets exactly as instructed by your healthcare provider.
- Give MAVYRET 1 time a day just before or after a snack or meal.
- **Do not** open the packet until ready to use.
- Mix the pellets with a small amount of recommended food and swallow (see Instructions for Use for list of recommended food).
- Swallow the food and oral pellets mixture within 15 minutes of preparation. **Do not** crush or chew the oral pellets.
- **Do not** store any leftover mixture (MAVYRET oral pellets mixed with food) for use at a later time. Throw away any unused portion.

#### **What are the possible side effects of MAVYRET?**

**MAVYRET can cause serious side effects, including:**

- **Hepatitis B virus reactivation.** See "What is the most important information I should know about MAVYRET?"
- **In people who had or have advanced liver problems before starting treatment with MAVYRET: rare risk of worsening liver problems, liver failure and death.** Your healthcare provider will check you for signs and symptoms of worsening liver problems during treatment with MAVYRET. Tell your healthcare provider right away if you have any of the following signs and symptoms:
 

◦ nausea	◦ diarrhea
◦ tiredness	◦ dark or brown (tea-colored) urine
◦ yellowing of your skin or white part of your eyes	◦ swelling or pain on the upper right side of your stomach area (abdomen)
◦ bleeding or bruising more easily than normal	◦ sleepiness
◦ confusion	◦ vomiting of blood
◦ dark, black, or bloody stool	◦ lightheadedness
◦ loss of appetite	

The most common side effects of MAVYRET include headache and tiredness.

These are not all the possible side effects of MAVYRET.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store MAVYRET?**

- Store MAVYRET at or below 86°F (30°C).
- Keep MAVYRET in its original package until you are ready to take it.

**Keep MAVYRET and all medicines out of the reach of children.**

#### **General information about the safe and effective use of MAVYRET**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use MAVYRET for a condition for which it was not prescribed. Do not give MAVYRET to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about MAVYRET that is written for health professionals.

**What are the ingredients in MAVYRET?****MAVYRET tablets**

**Active ingredients:** glecaprevir and pibrentasvir

**Inactive ingredients:** colloidal silicon dioxide, copovidone (type K 28), croscarmellose sodium, hypromellose 2910, iron oxide red, lactose monohydrate, polyethylene glycol 3350, propylene glycol monocaprylate (type II), sodium stearyl fumarate, titanium dioxide, and vitamin E (tocopherol) polyethylene glycol succinate. The tablets do not contain gluten.

**MAVYRET oral pellets:**

**Active ingredients:** glecaprevir and pibrentasvir

**Inactive ingredients:** colloidal silicon dioxide, copovidone (type K 28), croscarmellose sodium, hypromellose 2910, iron oxide red, iron oxide yellow, lactose monohydrate, polyethylene glycol/macrogol 3350, propylene glycol monocaprylate (type II), sodium stearyl fumarate, titanium dioxide, vitamin E (tocopherol) polyethylene glycol succinate. The oral pellets do not contain gluten.

Manufactured by AbbVie Inc., North Chicago, IL 60064.

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For more information go to [www.MAVYRET.com](http://www.MAVYRET.com) or call 1-800-633-9110.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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