



Patient Information Sheet

Entecavir (marketed as Baraclude™)

This is a summary of the most important information about Baraclude. For details, talk to your healthcare professional.

What is the most important information about Baraclude?

- **Lactic acidosis** (buildup of an acid in the blood). Lactic acidosis is a medical emergency and must be treated in the hospital. Call your healthcare professional right away if you get any of the following signs of lactic acidosis:
 - You feel very weak or tired.
 - You have unusual (not normal) muscle pain.
 - You have trouble breathing.
 - You have stomach pain with nausea and vomiting.
 - You feel cold, especially in your arms and legs.
 - You feel dizzy or light-headed.
 - You have a fast or irregular heartbeat.
- **Serious liver problems called hepatotoxicity**, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your healthcare professional right away if you get any of the following signs of liver problems:
 - Your skin or the white part of your eyes turns yellow (jaundice).
 - Your urine turns dark.
 - Your bowel movements (stools) turn light in color.
 - You don't feel like eating food for several days or longer.
 - You feel sick to your stomach (nausea).
 - You have lower stomach pain.
- **Stopping Baraclude may worsen your hepatitis B infection. Therefore:**
 - Take Baraclude exactly as prescribed.
 - Do not run out of Baraclude.
 - Do not stop Baraclude without talking to your healthcare professional.

What is Baraclude?

Baraclude is a prescription medicine used for chronic infection with hepatitis B virus (HBV) in adults who also have active liver damage.

- Baraclude will not cure HBV.
- Baraclude does not stop you from spreading HBV to others by having sex, sharing needles, or being exposed to your blood.
- Baraclude may lower the amount of HBV in the body.
- Baraclude may lower the ability of HBV to multiply and infect new liver cells.
- Baraclude may improve the condition of your liver.

It is important to stay under your healthcare professional's care while taking Baraclude. Your healthcare professional will test the level of the hepatitis B virus in your blood regularly.

Who Should Not Use Baraclude?

- Do not take Baraclude if you are allergic to entecavir or any of its ingredients.
- Baraclude has not been studied in children and is not recommended for anyone less than 16 years old.

What are The Risks?

See, "What is the most important information about Baraclude?"

- **Other common side effects include** headache, tiredness, dizziness, and nausea.

What Should I Tell My Health Care Professional?
Before you start taking Baraclude, tell your health care professional if you:

- have kidney problems
- are pregnant or planning to become pregnant
- are breastfeeding

Are There Any Interactions With Drugs or Foods?

Baraclude may interact with certain other medicines that leave the body through the kidneys. Know the medicines that you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Keep a list of them to show your healthcare professional and pharmacist.

How should I take Baraclude?

- Take Baraclude exactly as prescribed. Your dose will depend on whether you have been treated for HBV infection before and what medicine you took. Your dose may be lower if you have kidney problems.
- Take Baraclude once a day on an empty stomach to help it work better. Empty stomach means at least 2 hours after a meal and at least 2 hours before the next meal.
- Do not change your dose or stop taking Baraclude without talking to your healthcare professional. After you stop taking Baraclude, it is important to stay under your healthcare professional's care. Your healthcare provider will need to do regular blood tests to check your liver.

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