

Patient Information

Rx only

Baraclude[®] (BEAR ah klude)

(generic name = entecavir)

Tablets and Oral Solution

Read the Patient Information that comes with BARACLUDGE before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about BARACLUDGE?

1. Some people who have taken medicines like BARACLUDGE (a nucleoside analogue) have developed a serious condition called 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 provider 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.

2. Some people who have taken medicines like BARACLUDGE have developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). **Call your healthcare provider 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.

3. Your hepatitis B infection may get worse or become very serious if you stop BARACLUDE.

- Take BARACLUDE exactly as prescribed.
- Do not run out of BARACLUDE.
- Do not stop BARACLUDE without talking to your healthcare provider.

Your healthcare provider will need to monitor your health and do regular blood tests to check your liver if you stop BARACLUDE. Tell your healthcare provider right away about any new or unusual symptoms that you notice after you stop taking BARACLUDE.

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 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 provider's care while taking BARACLUDE. Your healthcare provider will test the level of the hepatitis B virus in your blood regularly.

Does BARACLUDE lower the risk of passing HBV to others?

BARACLUDE does not stop you from spreading HBV to others by sex, sharing needles, or being exposed to your blood. Talk with your healthcare provider about safe sexual practices that protect your partner. Never share needles. Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades. A shot (vaccine) is available to protect people at risk from becoming infected with HBV.

Who should not take BARACLUDE?

Do not take BARACLUDE if you are allergic to any of its ingredients. The active ingredient in BARACLUDE is entecavir. See the end of this leaflet for a complete list of ingredients in BARACLUDE. Tell your healthcare provider if you think you have had an allergic reaction to any of these ingredients.

BARACLUDE has not been studied in children and is not recommended for anyone less than 16 years old.

What should I tell my healthcare provider before I take BARACLUDE?

Tell your healthcare provider about all of your medical conditions, including if you:

- **have kidney problems.** Your BARACLUDE dose or dose schedule may need to be adjusted.
- **are pregnant or planning to become pregnant.** It is not known if BARACLUDE is safe to use during pregnancy. It is not known whether BARACLUDE helps prevent a pregnant mother from passing HBV to her baby. You and your healthcare provider will need to decide if BARACLUDE is right for you. If you use BARACLUDE while you are pregnant, talk to your healthcare provider about the BARACLUDE Pregnancy Registry.
- **are breast-feeding.** It is not known if BARACLUDE can pass into your breast milk or if it can harm your baby. Do not breast-feed if you are taking BARACLUDE.

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. BARACLUDE may interact with other medicines that leave the body through the kidneys.

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist.

How should I take BARACLUDE?

Take BARACLUDE exactly as prescribed. Your healthcare provider will tell you how much BARACLUDE to take. Your dose will depend on whether you have been

- treated for HBV infection before and what medicine you took. The usual dose of BARACLUDE Tablets is either 0.5 mg (one white tablet) or 1 mg (one pink tablet) once daily by mouth. The usual dose of BARACLUDE Oral Solution is either 10 mL or 20 mL once daily by mouth. **Your dose may be lower or you may take BARACLUDE less often than once a day 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. To help you remember to take your BARACLUDE, try to take it at the same time each day.
- If you are taking BARACLUDE Oral Solution, carefully measure your dose with the spoon provided, as follows:
 - 1) Hold the spoon in a vertical (upright) position and fill it gradually to the mark corresponding to the prescribed dose. Holding the spoon with the volume marks facing you, check that it has been filled to the proper mark.
 - 2) Swallow the medicine directly from the measuring spoon.
 - 3) After each use, rinse the spoon with water and allow it to air dry.
If you lose the spoon, call your pharmacist or healthcare provider for instructions.
- **Do not change your dose or stop taking BARACLUDE without talking to your healthcare provider. Your hepatitis B symptoms may get worse or become very serious if you stop taking BARACLUDE.** After you stop taking BARACLUDE, it is important to stay under your healthcare provider's care. Your healthcare provider will need to do regular blood tests to check your liver.
- **If you forget to take BARACLUDE**, take it as soon as you remember and then take your next dose at its regular time. If it is almost time for your next dose, skip the missed dose. Do not take two doses at the same time. Call your healthcare provider or pharmacist if you are not sure what to do.
- When your supply of BARACLUDE starts to run low, get more from your healthcare provider or pharmacy. **Do not run out of BARACLUDE.**
- **If you take more than the prescribed dose of BARACLUDE**, call your healthcare provider right away.

What are the possible side effects of BARACLUDE?

BARACLUDE may cause the following serious side effects (see “What is the most important information I should know about BARACLUDE?”):

- **lactic acidosis and liver problems.**
- **a worse or very serious hepatitis if you stop taking it.**

The most common side effects of BARACLUDE are headache, tiredness, dizziness, and nausea. Less common side effects include diarrhea, indigestion, vomiting, sleepiness, and trouble sleeping. In some patients, the results of blood tests that measure how the liver or pancreas is working may worsen.

These are not all the side effects of BARACLUDE. The list of side effects is **not** complete at this time because BARACLUDE is still under study. Report any new or continuing symptom to your healthcare provider. If you have questions about side effects, ask your healthcare provider. Your healthcare provider may be able to help you manage these side effects.

How should I store BARACLUDE?

- Store BARACLUDE Tablets or Oral Solution at room temperature, 59° to 86° F (15° to 30° C). They do not require refrigeration. Do not store BARACLUDE Tablets in a damp place such as a bathroom medicine cabinet or near the kitchen sink.
- Keep the container tightly closed. BARACLUDE Oral Solution should be stored in the original carton and protected from light.
- Throw away BARACLUDE when it is outdated or no longer needed by flushing tablets down the toilet or pouring the oral solution down the sink.
- **Keep BARACLUDE and all medicines out of the reach of children and pets.**

General information about BARACLUDE: Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use BARACLUDE for a condition for which it was not prescribed. Do not give BARACLUDE to other people, even if they have the same symptoms you have. It may harm them. The leaflet summarizes the most important information about BARACLUDE. If you would like more information, talk with your healthcare provider. You can ask

What are the ingredients in BARACLUDE?

Active Ingredient: entecavir

Inactive Ingredients in BARACLUDE Tablets: lactose monohydrate, microcrystalline cellulose, crospovidone, povidone, magnesium stearate, titanium dioxide, hypromellose, polyethylene glycol 400, polysorbate 80 (0.5-mg tablet only), and iron oxide red (1-mg tablet only).

Inactive Ingredients in BARACLUDE Oral Solution: maltitol, sodium citrate, citric acid, methylparaben, propylparaben, and orange flavor.

Bristol-Myers Squibb Company

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

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