

Patient Information
BARACLUE® (BEAR ah Klude)
(entecavir)
Tablets and Oral Solution

Read this Patient Information before you start taking BARACLUE 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 BARACLUE (entecavir)?

- Your hepatitis B virus infection may get worse if you stop taking BARACLUE.** This usually happens within 6 months after stopping BARACLUE.
 - Take BARACLUE exactly as prescribed.
 - Do not run out of BARACLUE.
 - Do not stop BARACLUE without talking to your healthcare provider.
 - Your healthcare provider should monitor your health and do regular blood tests to check your liver if you stop taking BARACLUE.
- If you have or get HIV that is not being treated with medicines while taking BARACLUE, the HIV virus may develop resistance to certain HIV medicines and become harder to treat.** You should get an HIV test before you start taking BARACLUE and anytime after that when there is a chance you were exposed to HIV.

BARACLUE can cause serious side effects including:

- Lactic acidosis (buildup of acid in the blood). Some people who have taken BARACLUE or medicines like BARACLUE (a nucleoside analogue) have developed a serious condition called lactic acidosis.** Lactic acidosis is a serious medical emergency that can cause death. Lactic acidosis must be treated in the hospital. Reports of lactic acidosis with BARACLUE generally involved patients who were seriously ill due to their liver disease or other medical condition.

Call your healthcare provider right away if you get any of the following signs or symptoms 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. Some people who have taken medicines like BARACLUE have developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Hepatomegaly with steatosis is a serious medical emergency that can cause death.**

Call your healthcare provider right away if you get any of the following signs or symptoms 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.

You may be more likely to get lactic acidosis or serious liver problems if you are female, very overweight, or have been taking nucleoside analogue medicines, like BARACLUE, for a long time.

What is BARACLUE?

BARACLUE is a prescription medicine used to treat chronic hepatitis B virus (HBV) in adults who have active liver damage.

- BARACLUE will not cure HBV.
- BARACLUE may lower the amount of HBV in the body.
- BARACLUE may lower the ability of HBV to multiply and infect new liver cells.
- BARACLUE may improve the condition of your liver.
- It is not known whether BARACLUE will reduce your chances of getting liver cancer or liver damage (cirrhosis), which may be caused by chronic HBV infection.
- It is not known if BARACLUE is safe and effective for use in children.

What should I tell my healthcare provider before taking BARACLUE?

Before you take BARACLUE, tell your healthcare provider if you:

- have kidney problems. Your BARACLUE dose or schedule may need to be changed.
- have received medicine for HBV before. Some people, especially those who have already been treated with certain other medicines for HBV infection, may develop resistance to BARACLUE. These people may have less benefit from treatment with BARACLUE and may have worsening of hepatitis after resistant virus appears. Your healthcare provider will test the level of the hepatitis B virus in your blood regularly.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if BARACLUE will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

Pregnancy Registry. If you take BARACLUE while you are pregnant, talk to your healthcare provider about how you can take part in the BARACLUE Pregnancy Registry. The purpose of the pregnancy registry is to collect information about the health of you and your baby.

- are breast-feeding or plan to breast-feed. It is not known if BARACLUE can pass into your breast milk. You and your healthcare provider should decide if you will take BARACLUE or breast-feed.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

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

How should I take BARACLUE?

- Take BARACLUE exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much BARACLUE to take.
- Your healthcare provider will tell you when and how often to take BARACLUE.
- **Take BARACLUE on an empty stomach,** at least 2 hours after a meal and at least 2 hours before the next meal.
- If you are taking BARACLUE Oral Solution, carefully measure your dose with the spoon provided, as follows:
 - 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.
 - Swallow the medicine directly from the measuring spoon.
 - 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 BARACLUE without talking to your healthcare provider.**
- **If you forget to take BARACLUE,** 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 BARACLUE starts to run low, call your healthcare provider or pharmacy for a refill. **Do not run out of BARACLUE (entecavir).**
- **If you take too much BARACLUE,** call your healthcare provider or go to the nearest emergency room right away.

What are the possible side effects of BARACLUE?

BARACLUE may cause serious side effects. See "What is the most important information I should know about BARACLUE?"

The most common side effects of BARACLUE include:

- headache
- tiredness
- dizziness
- nausea

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of BARACLUE. For more information, ask your healthcare provider or pharmacist.

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

How should I store BARACLUE?

- Store BARACLUE Tablets or Oral Solution at room temperature, between 59° F to 86° F (15° C to 30° C).
- Keep BARACLUE Tablets in a tightly closed container.
- Do not store BARACLUE Tablets in a damp place such as a bathroom medicine cabinet or near the kitchen sink.
- Store BARACLUE Oral Solution in the original carton, and keep BARACLUE Oral Solution out of the light.
- Safely throw away BARACLUE that is out of date or no longer needed. Dispose of unused medicines through community take-back disposal programs when available or place BARACLUE in an unrecognizable closed container in the household trash.

Keep BARACLUE and all medicines out of the reach of children.

General information about the safe and effective use of BARACLUE

BARACLUE does not stop you from spreading the hepatitis B virus (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.

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use BARACLUE for a condition for which it was not prescribed. Do not give BARACLUE to other people, even if they have the same symptoms you have. It may harm them. This Patient Information Leaflet summarizes the most important information about BARACLUE. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about BARACLUE that is written for healthcare professionals.

For more information, go to www.Baraclude.com or call 1-800-321-1335.

What are the ingredients in BARACLUE?

Active ingredient: entecavir

Inactive ingredients in BARACLUE Tablets: lactose monohydrate, microcrystalline cellulose, crospovidone, povidone, magnesium stearate.

Tablet film-coat: titanium dioxide, hypromellose, polyethylene glycol 400, polysorbate 80 (0.5-mg tablet only), and iron oxide red (1-mg tablet only).

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



Bristol-Myers Squibb

Bristol-Myers Squibb Company
 Princeton, NJ 08543 USA

This Patient Information Leaflet has been approved by the U.S. Food and Drug Administration.
 1195459B1 F0-B0001B-12-10 Rev December 2010