

BARACLUDGE® (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 (entecavir)?**1. Your hepatitis B virus infection may get worse or become very serious if you stop BARACLUDGE.**

- Take BARACLUDGE exactly as prescribed.
- Do not run out of BARACLUDGE.
- Do not stop BARACLUDGE 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 BARACLUDGE. Tell your healthcare provider right away about any new or unusual symptoms that you notice after you stop taking BARACLUDGE.

2. If you have or get HIV (human immunodeficiency virus) infection be sure to discuss your treatment with your doctor.

If you are taking BARACLUDGE to treat chronic hepatitis B and are not taking medicines for your HIV at the same time, some HIV treatments that you take in the future may be less likely to work. You are advised to get an HIV test before you start taking BARACLUDGE and anytime after that when there is a chance you were exposed to HIV. BARACLUDGE will not help your HIV infection.

3. 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 serious medical emergency that can lead to death. Lactic acidosis 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.

4. 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.

What is BARACLUDGE?

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

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

It is important to stay under your healthcare provider's care while taking BARACLUDGE. Some people, especially those who have already been treated with certain other medicines for HBV infection, may develop resistance to BARACLUDGE.

These people may have less benefit from treatment with BARACLUDGE 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.

Does BARACLUDGE lower the risk of passing HBV to others?

BARACLUDGE 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 BARACLUDGE?

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

BARACLUDGE 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 BARACLUDGE?

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

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

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

- Take BARACLUDGE exactly as prescribed. Your healthcare provider will tell you how much BARACLUDGE 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 BARACLUDGE Tablets is either 0.5 mg (one white tablet) or 1 mg (one pink tablet) once daily by mouth. The usual dose of BARACLUDGE Oral Solution is either 10 mL or 20 mL once daily by mouth. Your dose may be lower or you may take BARACLUDGE less often than once a day if you have kidney problems.
- **Take BARACLUDGE 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 BARACLUDGE, try to take it at the same time each day.
- If you are taking BARACLUDGE 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 BARACLUDGE without talking to your healthcare provider. Your hepatitis B symptoms may get worse or become very serious if you stop taking BARACLUDGE.** After you stop taking BARACLUDGE, 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.

BARACLUE® (entecavir)

- **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, get more from your healthcare provider or pharmacy. **Do not run out of BARACLUE (entecavir).**
- **If you take more than the prescribed dose of BARACLUE**, call your healthcare provider right away.

What are the possible side effects of BARACLUE?

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

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

The most common side effects of BARACLUE are headache, tiredness, dizziness, and nausea. Less common side effects include diarrhea, indigestion, vomiting, sleepiness, and trouble sleeping. There have also been occasional reports of rash and hair loss. 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 BARACLUE. The list of side effects is **not** complete at this time because BARACLUE 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 BARACLUE?

- Store BARACLUE Tablets or Oral Solution at room temperature, 59° to 86° F (15° to 30° C). They do not require refrigeration. Do not store BARACLUE Tablets in a damp place such as a bathroom medicine cabinet or near the kitchen sink.
- Keep the container tightly closed. BARACLUE Oral Solution should be stored in the original carton and protected from light.
- **Keep BARACLUE and all medicines out of the reach of children and pets at all times.** Do not keep medicine that is out of date or that you no longer need. Dispose of unused medicines through community take-back disposal programs when available or place BARACLUE in an unrecognizable closed container in the household trash.

General information about BARACLUE: Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. 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. The 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. You can also call 1-800-321-1335 or visit the BARACLUE website at www.Baraclude.com.

What are the ingredients in BARACLUE?

Active Ingredient: entecavir

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

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

