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546 **PATIENT INFORMATION**

547 **Baraclude[®]** (BEAR ah klude)

548 (generic name = **entecavir**)

549 **Tablets and Oral Solution**

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

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

554 1. **Some people who have taken medicines like BARACLUDGE (a nucleoside**
555 **analogue) have developed a serious condition called lactic acidosis** (buildup of an
556 acid in the blood). Lactic acidosis is a medical emergency and must be treated in the
557 hospital. **Call your healthcare provider right away if you get any of the following**
558 **signs of lactic acidosis.**

- 559 • You feel very weak or tired.
- 560 • You have unusual (not normal) muscle pain.
- 561 • You have trouble breathing.
- 562 • You have stomach pain with nausea and vomiting.
- 563 • You feel cold, especially in your arms and legs.
- 564 • You feel dizzy or light-headed.
- 565 • You have a fast or irregular heartbeat.

566 2. **Some people who have taken medicines like BARACLUDGE have developed**
567 **serious liver problems called hepatotoxicity**, with liver enlargement
568 (hepatomegaly) and fat in the liver (steatosis). **Call your healthcare provider right**
569 **away if you get any of the following signs of liver problems.**

- 570 • Your skin or the white part of your eyes turns yellow (jaundice).
- 571 • Your urine turns dark.
- 572 • Your bowel movements (stools) turn light in color.
- 573 • You don't feel like eating food for several days or longer.
- 574 • You feel sick to your stomach (nausea).
- 575 • You have lower stomach pain.

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

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

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

585 4. **If you have or get HIV (human immunodeficiency virus) infection be sure to**
586 **discuss your treatment with your doctor.** If you are taking BARACLUDE to treat
587 chronic hepatitis B and are not taking medicines for your HIV at the same time, some
588 HIV treatments that you take in the future may be less likely to work. You are advised
589 to get an HIV test before you start taking BARACLUDE and anytime after that when
590 there is a chance you were exposed to HIV. BARACLUDE will not help your HIV
591 infection.

592 **What is BARACLUDE?**

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

- 595 • BARACLUDE will not cure HBV.
- 596 • BARACLUDE may lower the amount of HBV in the body.
- 597 • BARACLUDE may lower the ability of HBV to multiply and infect new liver cells.
- 598 • BARACLUDE may improve the condition of your liver.

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

601 **Does BARACLUDE lower the risk of passing HBV to others?**

602 BARACLUDE does not stop you from spreading HBV to others by sex, sharing needles, or
603 being exposed to your blood. Talk with your healthcare provider about safe sexual practices
604 that protect your partner. Never share needles. Do not share personal items that can have blood

605 or body fluids on them, like toothbrushes or razor blades. A shot (vaccine) is available to
606 protect people at risk from becoming infected with HBV.

607 **Who should not take BARACLUDE?**

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

612 BARACLUDE has not been studied in children and is not recommended for anyone less than
613 16 years old.

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

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

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

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

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

631 **How should I take BARACLUDE?**

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- 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:

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- 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.

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- 2) Swallow the medicine directly from the measuring spoon.

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- 3) After each use, rinse the spoon with water and allow it to air dry.

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If you lose the spoon, call your pharmacist or healthcare provider for instructions.

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- **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** (entecavir).

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- **If you take more than the prescribed dose of BARACLUDGE**, call your healthcare provider right away.
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665 **What are the possible side effects of BARACLUDGE?**

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

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- **lactic acidosis and liver problems.**
 - **a worse or very serious hepatitis if you stop taking it.**
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670 The most common side effects of BARACLUDGE are headache, tiredness, dizziness, and
671 nausea. Less common side effects include diarrhea, indigestion, vomiting, sleepiness, and
672 trouble sleeping. **There have also been occasional reports of rash.** In some patients, the results
673 of blood tests that measure how the liver or pancreas is working may worsen.

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

678 **How should I store BARACLUDGE?**

- Store BARACLUDGE Tablets or Oral Solution at room temperature, 59° to 86° F (15° to 30° C). They do not require refrigeration. Do not store BARACLUDGE Tablets in a damp place such as a bathroom medicine cabinet or near the kitchen sink.
 - Keep the container tightly closed. BARACLUDGE Oral Solution should be stored in the original carton and protected from light.
 - **Keep BARACLUDGE 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 BARACLUDGE in an unrecognizable closed container in the household trash.
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688 **General information about BARACLUDGE:** Medicines are sometimes prescribed for
689 conditions other than those described in patient information leaflets. Do not use BARACLUDGE
690 for a condition for which it was not prescribed. Do not give BARACLUDGE to other people,
691 even if they have the same symptoms you have. It may harm them. The leaflet summarizes the
692 most important information about BARACLUDGE. If you would like more information, talk

693 with your healthcare provider. You can ask your healthcare provider or pharmacist for
694 information about BARACLUDE that is written for healthcare professionals. You can also call
695 1-800-321-1335 or visit the BARACLUDE website at *www.Baraclude.com*.

696 **What are the ingredients in BARACLUDE?**

697 **Active Ingredient:** entecavir

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

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

704 Bristol-Myers Squibb Company
705 Princeton, NJ 08543 USA

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