

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

PrBARACLUDE*
(entecavir)

This leaflet is Part III of a three-part “Product Monograph” published when BARACLUDE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about BARACLUDE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for

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

What it does

- 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 reduce the damage to the liver by HBV.

BARACLUDE will not cure HBV infection.

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.

When it should not be used

Do not take BARACLUDE if you are allergic to any of its ingredients. The active ingredient in BARACLUDE is entecavir. See “What the nonmedicinal ingredients are” 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 the medicinal ingredient is:

Entecavir

What the nonmedicinal ingredients are:

BARACLUDE tablets: lactose monohydrate, microcrystalline cellulose, croscopovidone, povidone, magnesium stearate, titanium dioxide, hypromellose, polyethylene glycol 400, polysorbate 80.
BARACLUDE Oral Solution: citric acid, maltitol, methylparaben, orange flavor, propylparaben and sodium citrate.

What dosage forms it comes in:

- BARACLUDE film-coated tablets
- BARACLUDE Oral Solution

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 to 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.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Severe worsening of hepatitis (liver inflammation) has occurred in patients who have stopped taking anti-hepatitis B therapy (including BARACLUDE). Your doctor will monitor your condition in this case and may resume therapy.

Lactic acidosis (increase in acid level of blood) and severe hepatomegaly with steatosis (enlarged fatty liver), including fatal cases have been reported in patients using medicines like BARACLUDE, either alone or in combination. 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 signs of lactic acidosis. (see below)

1. Some people who have taken medicines like BARACLUDE (a nucleoside analogue) have developed a serious condition called lactic acidosis (build up 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 BARACLUDE 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 of your eyes turns yellow (jaundice)
 - your urine turns dark
 - your bowel movements (stools) turn light in colour
 - 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.

If you have or get HIV (human immunodeficiency virus) infection be sure to discuss your treatment with your doctor. If you are taking BARACLUDE 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 BARACLUDE and anytime after that when there is a chance you were exposed to HIV. BARACLUDE will not help your HIV infection.

BEFORE you use BARACLUDE talk to your healthcare provider about all of your medical conditions, including if you:

- have had a liver transplant
- have kidney problems. Your doctor may need to adjust your BARACLUDE dose or dose schedule.
- have diabetes. The oral solution contains 6.5 mg/10 mL of maltitol as a sweetener.
- 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.
- are lactose intolerant. BARACLUDE tablets contain lactose. If you have been told that you have intolerance to some sugars, contact your doctor before taking this medicine.

Tell your healthcare provider about all the medicines you take including prescription and non-prescription 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.

INTERACTIONS WITH THIS MEDICATION

BARACLUDE may interact with other medicines that leave the body through the kidneys.

PROPER USE OF THIS MEDICATION

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.

Usual dose

The usual dose of BARACLUDGE Tablets in adults and children over 16 years of age is either one or two 0.5 mg tablets once daily by mouth. The usual dose of BARACLUDGE Oral Solution in adults and children over 16 years of age 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 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.
- When your supply of BARACLUDGE starts to run low, get more from your healthcare provider or pharmacy. Do not run out of BARACLUDGE.

Overdose

If you take more than the prescribed dose of BARACLUDGE, call your healthcare provider right away or contact your local poison control centre.

Missed Dose

If you forget to take BARACLUDGE, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

BARACLUDGE may cause the following serious side effects (see Warnings and Precautions).

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

The most common side effects of BARACLUDGE are headache, tiredness, dizziness, and nausea. Rash has also been reported. 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 BARACLUDGE. The list of side effects is not complete at this time because BARACLUDGE 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 TO STORE IT

Store BARACLUDGE Tablets or Oral Solution at room temperature, 15° to 30° C (59° F to 86° F). 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.

Discard BARACLUDGE when it is outdated or no longer needed by returning the unused portion to your pharmacist for proper disposal.

Keep BARACLUDGE and all medicines out of the reach of children and pets.

General Information

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 also call Bristol Myers Squibb Canada at telephone number 1-866-463-6267.

This leaflet was prepared by Bristol-Myers Squibb Canada

Last revised: 30 July 2009

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug, you may notify Canada Vigilance:

By toll-free telephone: 1-866-234-2345

By toll free fax: 1-866-678-6789

Online: www.healthcanada.gc.ca/medeffect

By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:

Canada Vigilance National Office
Marketed Health Products Safety and
Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL0701C
Ottawa, ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting the sponsor, Bristol-Myers Squibb Canada at 1-866-463-6267.