

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, crospovidone, povidone, magnesium stearate, titanium dioxide, hypromellose, polyethylene glycol 400, polysorbate 80.

What dosage forms it comes in:

- BARACLUDE film-coated tablets

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 nucleoside analogue medicines, including BARACLUDE, either alone or in combination. Reports of lactic acidosis with BARACLUDE often involved patients who were seriously ill due to their liver disease or other medical condition. 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 table Serious Side Effects and What to do About them).

Your hepatitis B 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.

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.

BEFORE you use BARACLUDGE 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 BARACLUDGE dose or dose schedule.
- 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.
- are lactose intolerant. BARACLUDGE 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.

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.

INTERACTIONS WITH THIS MEDICATION

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

PROPER USE OF THIS MEDICATION

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.

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. 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.
- 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

In case of drug overdosage, contact a healthcare practitioner (e.g. doctor) hospital emergency department or regional poison control centre, even if there are no symptoms.

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

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.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Lactic acidosis (high level of lactic acid in the blood) Symptoms:			
Feeling very weak or tired		√	
Unusual (not normal) muscle pain		√	
Trouble breathing		√	
Stomach pain with nausea and vomiting		√	
Feeling cold especially in arms and legs		√	
Feeling dizzy or lightheaded		√	
Fast or irregular heartbeat		√	
Worsening hepatitis (inflamed liver), liver enlargement (hepatomegaly) or fatty liver Symptoms:			
Skin or the white part of eyes turn yellow (jaundice)		√	
Dark urine		√	
Bowel movements (stools) turn light in colour		√	
Nausea		√	

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist	Stop taking drug and
Lower stomach pain		√
Loss of appetite for several days or longer		√

This is not a complete list of side effects. For any unexpected effects while taking BARACLUDGE, contact your doctor or pharmacist.

HOW TO STORE IT

Store BARACLUDGE Tablets at room temperature, 15° to 30° C (59° F to 86° F). Keep the bottle in outer carton to protect from light. 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. 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 BARACLUDGE for a condition for which it was not prescribed. Do not give BARACLUDGE to other people, even if they have the same symptoms you have. It may harm them. The leaflet summarizes the most important information about BARACLUDGE. 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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reactions reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

Note: Should you require information related to the management of side effects, contact your health professional. 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.

This leaflet was prepared by Bristol-Myers Squibb Canada

Last revised: 23 September 2020