

PART III: CONSUMER INFORMATION

Pr ACCEL-ENTECAVIR

Entecavir Tablets

0.5 mg

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

ABOUT THIS MEDICATION

What the medication is used for

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

What it does

- ACCEL-ENTECAVIR may lower the amount of HBV in the body
- ACCEL-ENTECAVIR may lower the ability of HBV to multiply and infect new liver cells
- ACCEL-ENTECAVIR may reduce the damage to the liver by HBV

ACCEL-ENTECAVIR will not cure HBV infection.

It is important to stay under your healthcare provider’s care while taking ACCEL-ENTECAVIR. 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 ACCEL-ENTECAVIR if you are allergic to any of its ingredients. The active ingredient in ACCEL-ENTECAVIR is entecavir. See “What the nonmedicinal ingredients are” for a complete list of ingredients in ACCEL-ENTECAVIR .

Tell your healthcare provider if you think you have had an allergic reaction to any of these ingredients.

ACCEL-ENTECAVIR 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: ACCEL-

ENTECAVIR tablets: crospovidone, hypromellose, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, polysorbate 80 and titanium dioxide.

What dosage forms it comes in:

- ACCEL-ENTECAVIR film-coated tablets

Does ACCEL-ENTECAVIR lower the risk of passing HBV to others?

ACCEL-ENTECAVIR 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.

WARNING 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 ACCEL-ENTECAVIR). 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 ACCEL-ENTECAVIR, either alone or in combination. Reports of lactic acidosis with ACCEL-ENTECAVIR 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 ACCEL-ENTECAVIR.

- take ACCEL-ENTECAVIR exactly as prescribed
- do not run out of ACCEL-ENTECAVIR
- do not stop ACCEL-ENTECAVIR 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 ACCEL-ENTECAVIR. Tell your healthcare provider right

away about any new or unusual symptoms that you notice after you stop taking ACCEL-ENTECAVIR.

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

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

ACCEL-ENTECAVIR may interact with other medicines that leave the body through the kidneys.

PROPER USE OF THIS MEDICATION

Take ACCEL-ENTECAVIR exactly as prescribed. Your healthcare provider will tell you how much ACCEL-ENTECAVIR 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 ACCEL-ENTECAVIR 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 ACCEL-ENTECAVIR less often than once a day, if you have kidney problems.

- Take ACCEL-ENTECAVIR 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 ACCEL-ENTECAVIR, try to take it at the same time each day.
- Do not change your dose or stop taking ACCEL-ENTECAVIR without talking to your healthcare provider. Your hepatitis B symptoms may get worse or become serious if you stop taking ACCEL-ENTECAVIR. After you stop taking ACCEL-ENTECAVIR, 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 ACCEL-ENTECAVIR starts to run low, get more from your healthcare provider or pharmacy. Do not run out of ACCEL-ENTECAVIR.

Overdose

If you think you have taken too much ACCEL-ENTECAVIR, contact your healthcare professional (e.g. doctor) hospital emergency department or regional poison control centre, even if there are no symptoms.

Missed Dose

If you forget to take ACCEL-ENTECAVIR, 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 entecavir 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.

15° to 30° C (59° F to 86° F). They do not require refrigeration.

Do not store ACCEL-ENTECAVIR tablets in a damp place such as a bathroom medicine cabinet or near the kitchen sink.

Keep the container tightly closed.

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

Keep out of the reach and sight of children.

General Information

Medicines are sometimes prescribed for conditions other than those described in patient information leaflets. Do not use ACCEL-ENTECAVIR for a condition for which it was not prescribed. Do not give ACCEL-ENTECAVIR to other people, even if they have the same symptoms you have. It may harm them. The leaflet summarizes the most important information about ACCEL-ENTECAVIR. If you would like more information, talk with your healthcare provider. You can also call Accel Pharma Inc. at telephone number 1-877-822-2235.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and get immediate medical help
	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		✓	
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 ACCEL-ENTECAVIR, contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to the Health Canada by:

- visiting the Web page on Adverse Reaction Reporting (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

Note: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at <http://www.accelpharma.com> or by calling 1-877-822-2235.

This leaflet was prepared by Accel Pharma Inc.

Last revised: May 21, 2021

HOW TO STORE IT

Store ACCEL-ENTECAVIR tablets at room temperature,