

PART III: CONSUMER INFORMATION

P^rAPO-ENTECAVIR

Entecavir Tablets USP

This leaflet is Part III of a three-part “Product Monograph” published when APO-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 APO-ENTECAVIR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for

APO-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

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

APO-ENTECAVIR will not cure HBV infection.

It is important to stay under your healthcare provider's care while taking APO-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 APO-ENTECAVIR if you are allergic to any of its ingredients. The active ingredient in APO-ENTECAVIR is entecavir.

See “What the nonmedicinal ingredients are” for a complete list of ingredients in APO-ENTECAVIR.

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

APO-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:

APO-ENTECAVIRtablets: lactose monohydrate,

Microcrystalline cellulose, Crospovidone, Copovidone, magnesium stearate, titanium dioxide, Hydroxypropyl Cellulose, Hydroxypropyl methylcellulose, Polyethylene glycol 8000.

What dosage forms it comes in:

APO-ENTECAVIR film-coated tablets

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

APO-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.

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 APO-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 nucleosides analogue medicines, including APO-ENTECAVIR, either alone or in combination. Reports of lactic acidosis with Entecavir Tablets often involved patients who were seriously ill due to their liver disease or other medical conditions. 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 APO-ENTECAVIR.

- take APO-ENTECAVIR exactly as prescribed
- do not run out of APO-ENTECAVIR
- do not stop APO-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 APO-ENTECAVIR. Tell your healthcare provider right away about any new or unusual symptoms that you notice after you stop taking APO-ENTECAVIR.

If you have or get HIV (human immunodeficiency

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

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

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

PROPER USE OF THIS MEDICATION

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

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

Overdose

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

Missed Dose

If you forget to take APO-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 APO-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.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist	Stop taking drug and

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	Only if severe	In all cases	seek immediate emergency medical attention
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 APO- ENTECAVIR, contact your doctor or pharmacist.

HOW TO STORE IT

Store APO-ENTECAVIR Tablets in a tightly closed container at 25°C, excursions permitted between 15°C to 30°C.

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

Keep the container tightly closed.

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

- Keep APO-ENTECAVIR 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 APO-ENTECAVIR for a condition for which it was not prescribed. Do not give APO-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 APO-ENTECAVIR. If you would like more information, talk with your healthcare provider. You can also call Apotex Inc, Canada at telephone number 1-800-667-4708.

Reporting Side Effects

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

- Visiting the Web page on Adverse Reaction Reporting (<https://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

If you want more information about APO-ENTECAVIR:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this patient medication information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.apotex.ca/products>, or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc, Canada.

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