

## Patient Information

### Entecavir (en-TEK-a-vir) Tablets

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

#### **What is the most important information I should know about Entecavir?**

**1. Your hepatitis B virus (HBV) infection may get worse if you stop taking Entecavir.**

This usually happens within 6 months after stopping entecavir.

- Take entecavir exactly as prescribed.
- Do not run out of entecavir.
- Do not stop entecavir without talking to your healthcare provider.
- Your healthcare provider should monitor your health and do regular blood tests to check your liver if you stop taking entecavir.

**2. If you have or get HIV that is not being treated with medicines while taking Entecavir, the HIV virus may develop resistance to certain HIV medicines and become harder to treat.** You should get an HIV test before you start taking entecavir and anytime after that when there is a chance you were exposed to HIV.

#### **Entecavir can cause serious side effects including:**

**3. Lactic acidosis (buildup of acid in the blood).** Some people who have taken Entecavir or medicines like Entecavir (a nucleoside analogue) have developed a serious condition called lactic acidosis. Lactic acidosis is a serious medical emergency that can cause death. Lactic acidosis must be treated in the hospital. Reports of lactic acidosis with entecavir generally involved patients who were seriously ill due to their liver disease or other medical condition.

#### **Call your healthcare provider right away if you get any of the following signs or symptoms 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.

**4. Serious liver problems.** Some people who have taken medicines like Entecavir have developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Hepatomegaly with steatosis is a serious medical emergency that can cause death.

#### **Call your healthcare provider right away if you get any of the following signs or symptoms of liver problems:**

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

You may be more likely to get lactic acidosis or serious liver problems if you are female, very overweight, or have been taking nucleoside analogue medicines, like entecavir, for a long time.

### **What is Entecavir?**

Entecavir is a prescription medicine used to treat chronic hepatitis B virus (HBV) in adults and children 2 years of age and older who have active liver disease.

- Entecavir will not cure HBV.
- Entecavir may lower the amount of HBV in the body.
- Entecavir may lower the ability of HBV to multiply and infect new liver cells.
- Entecavir may improve the condition of your liver.
- It is not known whether entecavir will reduce your chances of getting liver cancer or liver damage (cirrhosis), which may be caused by chronic HBV infection.
- It is not known if entecavir is safe and effective for use in children less than 2 years of age.

### **What should I tell my healthcare provider before taking Entecavir?**

Before you take entecavir, tell your healthcare provider if you:

- have kidney problems. Your entecavir dose or schedule may need to be changed.
- have received medicine for HBV before. Some people, especially those who have already been treated with certain other medicines for HBV infection, may develop resistance to entecavir. These people may have less benefit from treatment with entecavir and may have worsening of hepatitis after resistant virus appears. Your healthcare provider will test the level of the hepatitis B virus in your blood regularly.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if entecavir will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

**Antiretroviral Pregnancy Registry.** If you take entecavir while you are pregnant, talk to your healthcare provider about how you can take part in the Antiretroviral Pregnancy Registry. The purpose of the pregnancy registry is to collect information about the health of you and your baby.

- are breastfeeding or plan to breastfeed. It is not known if entecavir can pass into your breast milk. You and your healthcare provider should decide if you will take entecavir or breast-feed.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you have taken a medicine to treat HBV in the past.

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist when you get a new medicine.

#### **How should I take Entecavir?**

- Take entecavir exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much entecavir to take.
- Your healthcare provider will tell you when and how often to take entecavir.
- **Take Entecavir on an empty stomach**, at least 2 hours after a meal and at least 2 hours before the next meal.
- **Do not change your dose or stop taking Entecavir without talking to your healthcare provider.**
- **If you miss a dose of 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.
- When your supply of entecavir starts to run low, call your healthcare provider or pharmacy for a refill. **Do not run out of Entecavir.**
- **If you take too much Entecavir**, call your healthcare provider or go to the nearest emergency room right away.

#### **What are the possible side effects of Entecavir?**

**Entecavir may cause serious side effects.** See “**What is the most important information I should know about Entecavir?**”

#### **The most common side effects of Entecavir include:**

- headache
- tiredness
- dizziness
- nausea

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of entecavir. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

#### **How should I store Entecavir?**

- Store entecavir tablets at room temperature, at 77°F (25°C).
- Keep entecavir tablets in a tightly closed container.
- Store entecavir tablets in the original container and protect from light.

- Safely throw away entecavir that is out of date or no longer needed. Dispose of unused medicines through community take-back disposal programs when available or place entecavir in an unrecognizable closed container in the household trash.
- Bottles of 30's and 250's count comes with a child-resistant package.

**Keep Entecavir and all medicines out of the reach of children.**

**General information about the safe and effective use of Entecavir**

Entecavir does not stop you from spreading the hepatitis B virus (HBV) to others by sex, sharing needles, or being exposed to your blood. Talk with 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.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use entecavir for a condition for which it was not prescribed. Do not give entecavir to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about entecavir. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about entecavir that is written for health professionals.

For more information, go to: [www.accordhealthcare.us](http://www.accordhealthcare.us) or call Accord Healthcare Inc. at 1-866-941-7875.

**What are the ingredients in Entecavir?**

Active ingredient: entecavir

Inactive ingredients in entecavir tablets: colloidal silicon dioxide, microcrystalline cellulose, sodium starch glycolate, magnesium stearate.

Tablet film-coat: hypromellose, titanium dioxide, polyethylene glycol, and FD&C Red #40 (1 mg tablet only).

Manufactured By:  
EirGen Pharma Ltd  
Waterford, Ireland

Distributed By:  
Accord Healthcare Inc.,  
1009 Slater Road, Suite 210-B,  
Durham, NC 27703, USA.

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

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