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[Home](#) → [Drugs, Herbs and Supplements](#) → Entecavir

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Entecavir

pronounced as (en te' ka veer)

IMPORTANT WARNING:

Entecavir can cause serious or life-threatening damage to the liver and a condition called lactic acidosis (a buildup of acid in the blood). The risk that you will develop lactic acidosis may be higher if you are a woman, if you are overweight, or if you have been treated with medications for hepatitis B virus (HBV) infection for a long time. Tell your doctor if you have or have ever had liver disease. If you experience any of the following symptoms, call your doctor immediately: yellowing of the skin or eyes; dark-colored urine; light-colored bowel movements; difficulty breathing; stomach pain or swelling; nausea; vomiting; unusual muscle pain; loss of appetite for at least several days; lack of energy; extreme weakness or tiredness; feeling cold, especially in the arms or legs; dizziness or lightheadedness; or fast or irregular heartbeat.

Do not stop taking entecavir without talking to your doctor. When you stop taking entecavir, your hepatitis may get worse. This is most likely to happen during the first several months after you stop taking entecavir. Take entecavir exactly as directed. Be careful not to miss doses or run out of entecavir. If you experience any of the following symptoms after you stop taking entecavir, call your doctor immediately: extreme tiredness, weakness, nausea, vomiting, loss of appetite, yellowing of the skin or eyes, dark-colored urine, light-colored bowel movements, or muscle or joint pain.

If you have human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) that is not being treated with medications and you take entecavir, your HIV infection may become more difficult to treat. Tell your doctor if you have HIV or AIDS or if there is a chance that you have been exposed to HIV. Your doctor may test you for HIV infection before you begin treatment with entecavir and at any time during your treatment if there is a chance that you have been exposed to HIV. Entecavir will not treat HIV infection.

Keep all appointments with your doctor and the laboratory before, during, and for a few months after your treatment with entecavir. Your doctor will order certain tests to check your body's response to entecavir during this time.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Talk to your doctor about the risks of taking entecavir.

Why is this medication prescribed?

Entecavir is used to treat chronic (long-term) hepatitis B infection (swelling of the liver caused by a virus) in adults and children 2 years of age and older who have liver damage. Entecavir is in a class of medications called nucleoside analogs. It works by decreasing the amount of hepatitis B virus (HBV) in the body. Entecavir does not cure HBV and may not prevent complications of chronic hepatitis B such as cirrhosis of the liver or liver cancer. Entecavir does not prevent the spread of HBV to other people.

How should this medicine be used?

Entecavir comes as a tablet and solution (liquid) to take by mouth. It is usually taken once a day on an empty stomach, at least 2 hours after a meal and at least 2 hours before the next meal. Take entecavir at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take entecavir exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

To use the entecavir oral solution, follow these steps:

1. Hold the spoon that came with your medication upright and slowly fill it with entecavir solution up to the mark that matches your dose.
2. Hold the spoon with the volume marks facing you and check to see that the top of the liquid is level with the mark that matches your dose.
3. Swallow the medication right from the measuring spoon. Do not mix the medication with water or any other liquid.
4. Rinse the spoon with water after each use, and allow it to air dry.
5. Put the spoon in a safe place where it will not get lost because you will need to use it every time you take your medication. If you do lose the dosing spoon, call your doctor or pharmacist.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking entecavir,

- tell your doctor and pharmacist if you are allergic to entecavir, or any other medications, or any of the ingredients in entecavir tablets or oral solution. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: aminoglycoside antibiotics such as amikacin, gentamicin, streptomycin, and tobramycin (Tobi); or medications to prevent rejection of a transplanted organ such as cyclosporine (Gengraf, Neoral, Sandimmune) or tacrolimus (Prograf). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor if you have had a liver transplant (surgery to replace a diseased liver) or if you have or have ever had kidney disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking entecavir, call your doctor. Do not breastfeed while you are taking entecavir.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking entecavir.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Entecavir may cause side effects. Tell your doctor if this symptom is severe or does not go away:

- headache

Some side effects can be serious. If you experience any of the symptoms listed in the IMPORTANT WARNING section, call your doctor immediately.

Entecavir may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children and pets. Store it at room temperature and away from excess heat, light, and moisture (not in the bathroom medicine cabinet or near the kitchen sink).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Baraclude[®]

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