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URL of this page: <https://medlineplus.gov/druginfo/meds/a607045.html>

Telbivudine

pronounced as (tel biv' ue deen)

Notice:

Telbivudine is no longer available in the U.S.. If you are currently using telbivudine, you should call your doctor to discuss switching to another treatment.

IMPORTANT WARNING:

Telbivudine can cause serious or life-threatening damage to the liver and a condition called lactic acidosis (a build-up of an acid in the blood). Tell your doctor if you drink or have ever drunk large amounts of alcohol, if you use or have ever used injectable street drugs, and if you have or have ever had cirrhosis (scarring) of the liver or any liver disease other than hepatitis B. Tell your doctor and pharmacist if you are taking or have taken the following medications: acetaminophen (Tylenol, others); cholesterol-lowering medications (statins); iron products; isoniazid (INH, Nydravid); medications to treat human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS); methotrexate (Rheumatrex); niacin (nicotinic acid); or rifampin (Rifadin, Rimactane). 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 telbivudine without talking to your doctor. When you stop taking telbivudine your hepatitis may get worse. This is most likely to happen during the first several months after you stop taking telbivudine. Be careful not to miss doses or run out of telbivudine. Refill your prescription at least 5 days before you expect that you will need the new supply of medication. If you experience any of the following symptoms after you stop taking telbivudine, call your doctor immediately: extreme tiredness, weakness, nausea, vomiting, loss of appetite, yellowing of the skin or eyes, dark-colored urine, or light-colored bowel movements.

Keep all appointments with your doctor and the laboratory before, during, and after your treatment with telbivudine. Your doctor will order certain tests to check your body's response to telbivudine

during this time.

Talk to your doctor about the risks of taking telbivudine.

Why is this medication prescribed?

Telbivudine is used for chronic (long term) hepatitis B infection (swelling of the liver caused by a virus) in people who may also show signs of liver damage. Telbivudine is in a class of medications called nucleoside analogues. It works by decreasing the amount of hepatitis B virus (HBV) in the body. Telbivudine does not cure hepatitis B and may not prevent complications of chronic hepatitis B, such as cirrhosis of the liver or liver cancer. Telbivudine does not prevent the spread of hepatitis B to other people through sexual contact, sharing needles, or contact with blood.

How should this medicine be used?

Telbivudine comes as a tablet to take by mouth. It is usually taken once a day with or without food. Take telbivudine 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 telbivudine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

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

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 telbivudine,

- tell your doctor and pharmacist if you are allergic to telbivudine or any other medications.
- 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: chloroquine (Aralen); erythromycin (E.E.S., E-Mycin, Erythrocin); fenofibrate (Antara, Lofibra, Triglide); gemfibrozil (Lopid); hydroxychloroquine (Plaquenil); medications to prevent rejection of a transplanted organ, such as cyclosporine (Neoral, Sandimmune) or tacrolimus (Prograf); medications to treat fungal infections such as fluconazole (Diflucan), itraconazole (Sporanox), ketoconazole (Nizoral), posaconazole (Noxafil), or voriconazole (Vfend); oral steroids such as dexamethasone (Decadron, Dexone), methylprednisolone (Medrol), and prednisone; (Deltasone), penicillamine (Cuprimine); probenecid; or zidovudine (AZT, Retrovir, in Combivir, in Trizivir). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- Tell your doctor if you have or have ever had a liver transplant (surgery to replace a diseased liver), or kidney disease.
- Tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking telbivudine, call your doctor. Do not breastfeed while you are taking telbivudine.

- If you are having surgery, including dental surgery, tell the doctor or dentist that you are taking telbivudine.

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?

Telbivudine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- diarrhea
- back or joint pain
- difficulty falling asleep or staying asleep
- itching
- rash

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

- muscle aches, pain, weakness, or tenderness

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

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 and moisture (not in the bathroom).

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.

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>]

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?

Keep all appointments with your doctor and the laboratory.

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

- Tyzeka[®]

Last Revised - 05/15/2018

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National Library of Medicine 8600 Rockville Pike, Bethesda, MD 20894 U.S. Department of Health and Human Services
National Institutes of Health

Page last updated: 25 March 2022