



Patient Information Sheet

Telbivudine (marketed as Tyzeka)

This is a summary of the most important information about Tyzeka. For details, talk to your healthcare professional.

What Is Tyzeka?

Tyzeka is a prescription medicine used for chronic hepatitis B virus (HBV) in adults who also have active liver damage.

- Tyzeka will not cure HBV
- Tyzeka may lower the amount of HBV in the body
- Tyzeka may lower the ability of HBV to multiply and infect new liver cells
- Tyzeka may improve the condition of your liver
- Tyzeka does not stop you from spreading 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.
- Tyzeka has not been studied in children and is not recommended for anyone less than 16 years old

Who Should Not Take Tyzeka?

- You should not take Tyzeka if you are allergic to telbivudine or any of the other ingredients in Tyzeka.
- Tyzeka is not recommended for anyone less than 16 years old.

What Are The Risks?

The following are the major potential risks and side effects of Tyzeka therapy. However, this list is not complete.

Tyzeka can cause serious side effects such as:

- ***lactic acidosis.*** Some people who have taken medicines like Tyzeka have developed a serious condition called lactic acidosis. Lactic acidosis is build up of acid in the blood. It is a medical emergency and must be treated in the hospital. Call your health care professional right away if you get any of the following signs of lactic acidosis:
 - you feel very weak or tired
 - you have unusual 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
- ***liver problems.*** Some people who take medicines like Tyzeka have developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your health care professional right away if you get any of the following signs 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
- ***muscle pain, weakness, or tenderness (myopathy).*** Some people who have taken medicines like Tyzeka have developed persistent unexplained muscle pain, muscle weakness, or muscle tenderness. If you develop any of these symptoms, call your health care professional right away.
- ***worsening of hepatitis after stopping Tyzeka.*** Your hepatitis B infection may get worse or become very serious if you stop taking Tyzeka. You should:
 - take your Tyzeka exactly as prescribed
 - do not stop taking Tyzeka without talking to your healthcare professional
 - be sure to refill your prescription or talk to your healthcare provider if you are running low on Tyzeka. Do not run out of Tyzeka.
 - Your healthcare professional will need to monitor your health and do regular blood tests to check your liver if you stop taking Tyzeka. Tell your health care professional right away about any new or unusual symptoms that you notice after you stop taking Tyzeka.
- ***Some common side effects that may occur with Tyzeka include:***
 - tiredness
 - headache
 - fever
 - muscle related symptoms
 - stomach pain
 - joint pain
 - diarrhea
 - cough





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You should report any new or continuing symptom to your healthcare professional. This list of side effects is **not** complete. Ask your doctor for more information. It is important to stay under your doctor's care while taking Tyzeka. Your doctor will test the level of the hepatitis B virus in your blood regularly.

What Should I Tell My Healthcare Professional?

Before you start taking Tyzeka, tell your healthcare professional about all of your medical conditions, including if you:

- have kidney problems. You may need a lower dose of Tyzeka.
- are pregnant or planning to become pregnant. It is not known if Tyzeka is safe to use during pregnancy. It is not known whether Tyzeka helps prevent a pregnant mother from passing HBV to her baby. You and your health care professional will need to decide if Tyzeka is right for you. If you use Tyzeka while you are pregnant, talk to your healthcare professional.
- are breast-feeding. It is not known if Tyzeka can pass into your breast milk or if it can harm your baby.

Can Other Medicines Or Food Affect Tyzeka?

Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Tyzeka may interact with

other medicines that leave the body through the kidneys. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

How Do I Take Tyzeka?

- Take Tyzeka exactly as prescribed. Your healthcare professional will tell you how much Tyzeka to take.
- Do not change your dose or stop taking Tyzeka without talking to your doctor. Your hepatitis B symptoms may get worse or become very serious if you stop taking Tyzeka.
- If you forget to take Tyzeka, 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 professional if you are not sure what to do.
- When your supply of Tyzeka starts to run low, get more from your healthcare professional. Do not run out of Tyzeka.
- If you take more than the prescribed dose of Tyzeka, call your healthcare provider right away.

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Tyzeka FDA Approved: 10/2006

