

Patients should be advised that Tyzeka is not a cure for hepatitis B, that the long-term treatment benefits of Tyzeka are unknown at this time. In particular, the relationship of initial treatment response to outcomes such as hepatocellular carcinoma and decompensated cirrhosis is unknown.

Patients should be informed that deterioration of liver disease may occur in some cases if treatment is discontinued, and that they should discuss any change in regimen with their physician.

Patients should be advised that treatment with Tyzeka has not been shown to reduce the risk of transmission of HBV to others through sexual contact or blood contamination. HBV prevention strategies should be discussed with patients, including safe sexual practices, and avoidance of needle sharing or sharing any personal items which may contain residual blood or body fluids, such as razor blades or toothbrushes. Additionally, a vaccine is available for prevention of hepatitis B infection in susceptible individuals.

Patients on a low sodium diet should be advised that Tyzeka oral solution contains approximately 47 mg of sodium per 600 mg dose (30 mL).

Patients should be advised to dispose of unused or expired Tyzeka by using a community pharmaceutical take-back disposal program, or by placing unused Tyzeka in a closed container, such as a sealed bag, into household trash. All identifying information should be removed from the original Tyzeka container prior to disposal.

FDA Approved Patient Labeling

MEDICATION GUIDE

Tyzeka[®] (Tie-zee'-ka)

(telbivudine)

Tablets

Tyzeka

(telbivudine)

Oral Solution

Read this Medication Guide carefully before you start taking Tyzeka and each time you refill your prescription. There may be new information. The information contained in this Medication Guide 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 Tyzeka?

Tyzeka can cause serious side effects, including:

Lactic Acidosis (build-up of an acid in the blood). Lactic acidosis can occur in people who take medicines like Tyzeka (a nucleoside analogue). Lactic acidosis is a serious medical emergency that can lead to death. Lactic acidosis must be treated in the hospital. Women, and people who are obese, or who have taken nucleoside analogues like Tyzeka for long periods of time may be at higher risk for lactic acidosis.

Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. Call your healthcare provider right away if you get any of the following symptoms which could be signs 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.

Liver problems. Serious liver problems have occurred in some people who take medicines like Tyzeka. This includes liver enlargement (hepatomegaly) and fat in the liver (steatosis).

Call your healthcare provider right away if you get any of these 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 do not feel like eating food for several days or longer.
- You feel sick to your stomach (nausea).
- You have lower stomach pain.

Muscle problems (myopathy). Tyzeka can cause muscle problems, including unexplained muscle pain, muscle weakness or muscle tenderness. Serious muscle problems can occur, including muscle breakdown (rhabdomyolysis). Muscle breakdown can lead to kidney damage. Tell your healthcare provider right away if you have unexplained muscle aches, pain, tenderness, or weakness.

Nerve problems. People who take Tyzeka alone or with the injectable medicine Pegasys[®] (pegylated interferon alfa-2a) or any type of injectable interferon product can have nerve problems such as continuing numbness, tingling, burning sensations in the arms or legs (peripheral neuropathy), or problems walking. Call your healthcare provider right away if you have any of these symptoms.

If you take Tyzeka with Pegasys[®] (pegylated interferon alfa-2a) or any type of injectable interferon product, your chance of having nerve problems may be higher and the nerve problems may be more severe. Be sure to tell your healthcare provider or pharmacist if you are also being treated with any type of injectable interferon for chronic hepatitis B or C. Check with your healthcare provider if you are not sure whether you are taking an injectable interferon product.

Worsening of your hepatitis B infection. Your hepatitis B infection may get worse or become very serious if you stop taking Tyzeka.

- Take your Tyzeka exactly as prescribed.
- Do not let your Tyzeka run out. Refill your prescription or talk to your healthcare provider before your Tyzeka is all gone.
- Do not stop taking your Tyzeka 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 taking Tyzeka. Tell your healthcare provider right away about any new or unusual symptoms that happen after you stop taking Tyzeka.

What is Tyzeka?

Tyzeka is a prescription medicine used for chronic infection with hepatitis B virus (HBV) in people 16 years of age and older 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.

It is not known if Tyzeka is safe and effective in children younger than age 16.

What should I tell my healthcare provider before I take Tyzeka?

Tell your healthcare provider about all of your medical conditions, including if you:

- have kidney problems. You may need a lower dose of Tyzeka.
- have any allergies.
- 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 healthcare provider will need to decide if Tyzeka is right for you. If you use Tyzeka while you are pregnant, talk to your healthcare provider.
- are breast-feeding. It is not known if Tyzeka can pass into your breast milk or if it can harm your baby. Do not breast-feed if you are taking Tyzeka.

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. Tyzeka may interact with other medicines that leave the body through the kidneys.

Especially tell your healthcare provider or pharmacist if you are also being treated with Pegasys[®] (pegylated interferon alfa-2a), or any type of injectable interferon product for chronic hepatitis B or C. (See “What is the most important information I should know about Tyzeka?”)

Tyzeka Oral Solution contains sodium. If you are on a low sodium diet, ask your healthcare provider for advice. Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist.

How should I take Tyzeka?

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, like toothbrushes or razor blades. A shot (vaccine) is available to protect people at risk from becoming infected with HBV, such as partners of patients with HBV.

- Take Tyzeka exactly as prescribed. Your healthcare provider will tell you how much Tyzeka to take. The usual dose of Tyzeka is 600 mg one time each day. Your dose may be lower if you have kidney problems.
- Tyzeka may be taken with or without food.
- To help you remember to take your Tyzeka, try to take it at the same time each day.
 - Do not change your dose or stop taking Tyzeka without talking to your healthcare provider first. See “What is the most important information I should know about Tyzeka?”
 - Tell your healthcare provider if you have trouble swallowing tablets. Tyzeka also comes as a liquid (oral solution) that you can drink. See the end of this Medication Guide for detailed *Patient Instructions for Use* for the right way to take Tyzeka oral solution.
 - If you forget to take Tyzeka, take it as soon as you remember and then take your next dose at the 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.
 - If you take more than your prescribed dose of Tyzeka, call your healthcare provider right away.

It is important to stay under your healthcare provider's care while taking Tyzeka. Your healthcare provider will regularly test the level of the hepatitis B virus in your blood.

What are the possible side effects of Tyzeka?

Tyzeka can cause serious side effects. (See "What is the most important information I should know about Tyzeka?").

Common side effects of Tyzeka include:

- tiredness
- headache
- cough
- diarrhea
- stomach area (abdominal) pain
- nausea
- sore throat
- joint pain
- fever
- skin rash
- back pain
- dizziness
- muscle aches
- upset stomach
- trouble sleeping
- stomach area (abdominal) swelling
- certain abnormal blood tests

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of Tyzeka. Your healthcare provider or pharmacist can give you a more complete list.

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

How should I store Tyzeka?

- Store Tyzeka Tablets and Oral Solution in the original bottle at room temperature, 59°F to 86°F (15° to 30°C).
- Do not store Tyzeka Tablets in a damp place such as a bathroom medicine cabinet or near the kitchen sink.
- Do not freeze Tyzeka Oral Solution.
- Use Tyzeka Oral Solution within 2 months after opening the bottle.
- Keep the bottle closed tightly.
- Throw away Tyzeka when it is outdated or no longer needed by taking Tyzeka to a community take-back disposal program, if available, or by placing Tyzeka in a closed container (such as a sealed bag) in the household trash. Remove all identifying information from the original Tyzeka container before throwing it out.

Keep Tyzeka and all medicines out of the reach of children.

General information about Tyzeka

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

This Medication Guide summarizes the most important information about Tyzeka. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Tyzeka that is written for healthcare professionals. For more information call 1-877-889-9352 or go to www.Tyzeka.com.

What are the ingredients in Tyzeka?

Active Ingredient: telbivudine

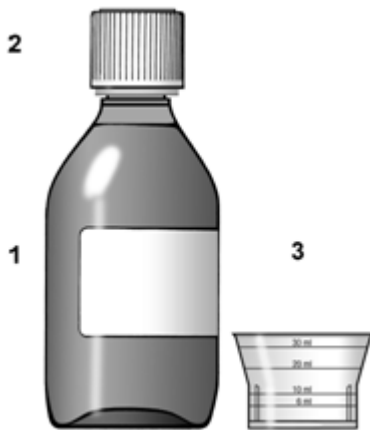
Inactive Ingredients in Tyzeka Tablets: colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate. The tablet coating contains titanium dioxide, polyethylene glycol, talc and hypromellose.

Inactive Ingredients in Tyzeka Oral Solution: citric acid anhydrous, benzoic acid, passion fruit flavor, sodium saccharin, sodium hydroxide, and purified water. A 600 mg dose (30 mL) of Tyzeka oral solution contains about 47 mg of sodium.

Patient Instructions for Use

Make sure that you read, understand and follow these instructions carefully so that you take Tyzeka oral solution the right way.

1. Supplies needed to take a dose of Tyzeka oral solution



To take your dose of Tyzeka you will need:

1. Bottle containing the medicine.
2. Child-resistant cap.
3. Oral dosing cup with 6, 10, 20 and 30 mL markings.

See Figure 1.

Figure 1

2. Important Information

- **Do not** pour any extra medicine back into the bottle. This will help prevent contamination.
- Close the bottle right away after use.
- Clean the dosing cup with clean water after each use.
- Keep the dosing cup dry between uses.
- The dosing cup is intended for measurement of Tyzeka oral solution only.

3. Prepare a dose of Tyzeka oral solution using the dosing cup

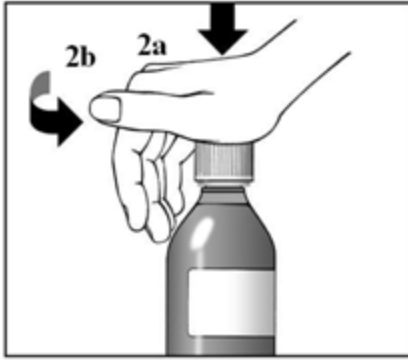


Figure 2a and 2b

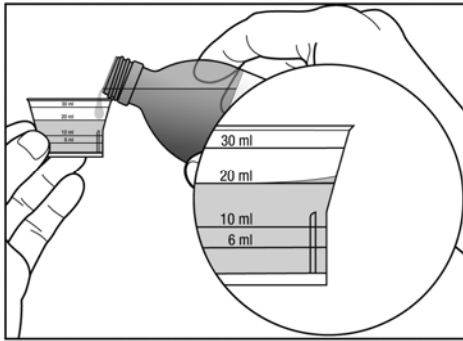


Figure 3

1. Remove the dosing cup from the cap.
2. Press down and turn the child-resistant cap at the same time, to open the bottle. See Figure 2a and 2b.

3. Before you pour the solution, check for the marking on the dosing cup that matches the amount of medicine that has been prescribed.
4. Hold the dosing cup at eye level. This will help to make sure that you measure the right amount of medicine. Carefully and slowly pour the prescribed amount of solution from the bottle into the dosing cup, until the solution reaches the line that matches the correct line on the dosing cup. See Figure 3.

If you pour too much medicine into the cup, pour the extra medicine into the sink. Do not pour it back into the bottle.

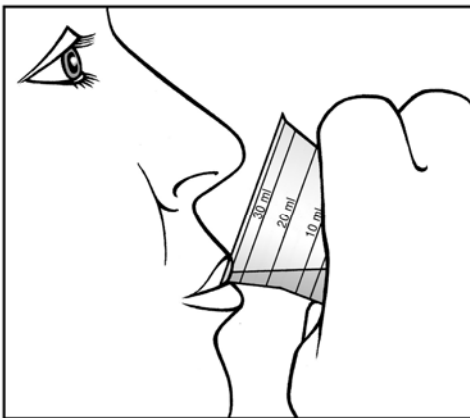


Figure 4

5. Take the medicine right away. See Figure 4.
6. Close the bottle tightly.

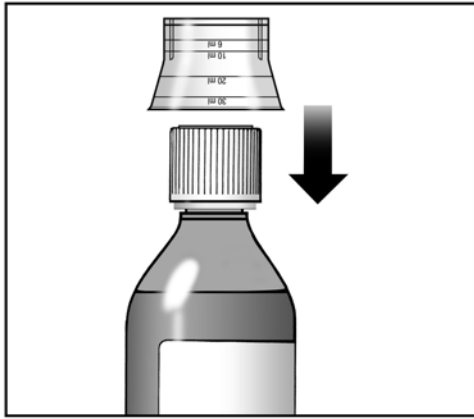


Figure 5

7. Rinse the dosing cup with clean water.
8. Dry the dosing cup using a dry, clean tissue before you put it back onto the cap. See Figure 5.

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This Medication Guide has been approved by the U.S. Food and Drug Administration

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