

MEDICATION GUIDE

KETEK® (KEE tek)
(telithromycin)
Tablets

Rx Only

Read this Medication Guide before you start taking KETEK and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT KETEK?

KETEK can cause serious side effects, including:

- **Worsening of myasthenia gravis symptoms in people who already have myasthenia gravis (a disease which causes muscle weakness). Worsening of myasthenia gravis symptoms, including life-threatening breathing problems, have happened in people with myasthenia gravis after taking KETEK. Some life-threatening breathing problems have caused death. Do not take KETEK if you have myasthenia gravis.**

WHAT IS KETEK?

KETEK is a prescription medication used to treat mild to moderate community-acquired pneumonia in adults 18 years of age and older.

- KETEK is only used to treat certain types of bacteria and is not meant for use to treat all types of bacterial infections. It is not known if KETEK is safe and effective in children.

Who should not take KETEK?

Do not take KETEK if you:

- have myasthenia gravis.
- have had liver problems or yellowing of your eyes and/or skin (jaundice) while taking KETEK or macrolide antibacterials.
- are allergic to KETEK, or macrolide antibacterials.
- take cisapride or pimozide.
- take colchicine and have kidney or liver problems.

What should I tell my doctor before taking KETEK?

Before you take KETEK, tell your doctor if you:

- have or have had liver or kidney problems
- have a heart problem called "QTc prolongation" or have a family history of QTc prolongation
- have other heart problems
- are pregnant or plan to become pregnant. It is not known if KETEK will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed. It is not known if KETEK passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take KETEK.

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking KETEK with other medicines can cause serious side effects. Ask your doctor for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take KETEK?

- Take KETEK exactly as your doctor tells you to take it.
- If you have kidney problems, your doctor may prescribe a lower dose of KETEK for you.
- Take KETEK with or without food.

- If you take too much KETEK, call your doctor, or go to the nearest hospital emergency room right away.

What should I avoid while taking KETEK?

- **Do not** drive, operate heavy machinery, or do other dangerous activities until you know how KETEK affects you.

What are the possible side effects of KETEK?

KETEK may cause serious side effects, including:

- See "What is the most important information I should know about KETEK?"
- **severe liver problems and severe liver damage (hepatotoxicity) that can lead to liver transplant or death.** Severe liver problems can happen while you take KETEK, even after a few doses or right after you stop taking it. Symptoms of liver problems may include:
 - loss of appetite
 - increased tiredness
 - nausea
 - yellowing of your skin or white of your eyes
 - dark colored urine (tea colored)
 - light colored stools
 - right upper belly (abdomen) pain
- **a heart problem called QTc prolongation that can lead to death.** Symptoms of QTc prolongation include fainting and fast heartbeat (heart palpitations). Call your doctor right away if you have these symptoms.
- **vision problems.** KETEK may cause you to have blurred vision, trouble focusing your eyes, and double vision. You may especially notice vision problems if you look quickly between objects close to you and objects far away from you.
- **fainting.** KETEK may cause you to faint, especially if you also have nausea, vomiting, and lightheadedness (vagal syndrome). See "What should I avoid while taking KETEK?"
- **drug interaction with colchicine in people with normal kidney and liver function that may lead to death.**
- **severe muscle damage (rhabdomyolysis).** KETEK may cause rhabdomyolysis when you also take certain medicines used to treat high levels of cholesterol in your blood. These medicines include:
 - simvastatin
 - lovastatin
 - atorvastatin
- **low blood pressure, slow heart rate, and fainting.** KETEK may cause you to have low blood pressure, a slow heart rate, and fainting when you also take certain medicines called calcium channel blockers. Calcium channel blockers include:
 - verapamil
 - amlodipine
 - diltiazem
 - or other medicines containing these products
- **an intestinal infection (Clostridium difficile-associated diarrhea).** *Clostridium difficile*-associated diarrhea can happen up to 2 months after you have stopped taking KETEK. Symptoms of *Clostridium difficile*-associated diarrhea may include:
 - watery diarrhea
 - diarrhea that does not go away
 - bloody stools
 - stomach cramps
 - fever

Stop taking KETEK and call your doctor right away if you have any of these symptoms listed above. Do not take another dose of KETEK unless your doctor tells you to.

The most common side effects of KETEK include:

- diarrhea
- nausea
- dizziness
- vomiting

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

These are not all of the possible side effects of KETEK. For more information ask your doctor or pharmacist.

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 KETEK?

- Store KETEK tablets at room temperature, between 59°F to 86°F (15°C to 30°C).
- **Keep KETEK and all medicines out of the reach of children.**

General information about the safe and effective use of KETEK

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

This Medication Guide summarizes the most important information about KETEK. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about KETEK that is written for health professionals. For more information, go to www.KETEK.com or call 1-800-446-6267.

What are the ingredients in KETEK?

Active Ingredient: telithromycin

Inactive Ingredients: croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, red ferric oxide, talc, titanium dioxide, and yellow ferric oxide

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

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A SANOFI COMPANY

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