

MEDICATION GUIDE  
**KETEK® (KEE tek) Tablets**  
(telithromycin)

READ THE MEDICATION GUIDE THAT COMES WITH KETEK BEFORE YOU START TAKING IT. TALK TO YOUR DOCTOR IF YOU HAVE ANY QUESTIONS ABOUT KETEK. THIS MEDICATION GUIDE DOES NOT TAKE THE PLACE OF TALKING WITH YOUR DOCTOR ABOUT YOUR MEDICAL CONDITION OR TREATMENT.

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

1. **Do not take KETEK if you have Myasthenia Gravis (a rare disease which causes muscle weakness). Worsening of myasthenia gravis symptoms including life-threatening breathing problems have happened in patients with myasthenia gravis after taking KETEK in some cases leading to death.**

**KETEK can cause other serious side effects, including:**

2. **SEVERE LIVER DAMAGE (HEPATOXICITY). SEVERE LIVER DAMAGE, IN SOME CASES LEADING TO A LIVER TRANSPLANT OR DEATH HAS HAPPENED IN PATIENTS TREATED WITH KETEK. SEVERE LIVER DAMAGE HAS HAPPENED DURING TREATMENT, EVEN AFTER A FEW DOSES, OR RIGHT AFTER TREATMENT WITH KETEK HAS ENDED.**

**Stop KETEK and call your doctor right away if you have signs of liver problems. Do not take another dose of KETEK unless your doctor tells you to do so.**

**Signs of liver problems include:**

- increased tiredness
- loss of appetite
- yellowing of the skin and/or eyes
- right upper belly pain
- light-colored stools
- dark urine
- itchy skin

Do not take KETEK if you have ever had side effects of the liver while taking KETEK or macrolide antibiotics. Macrolide antibiotics include erythromycin, azithromycin (Zithromax®), clarithromycin (Biaxin®) or dirithromycin (Dynabac®).

3. **Vision problems.** KETEK may cause blurred vision, trouble focusing, and double vision. You may notice vision problems if you look quickly from near objects to far objects.
4. **Fainting.** You may faint especially if you are also having nausea, vomiting, and lightheadedness.
  - BE AWARE THAT VISION PROBLEMS AND FAINTING WHILE TAKING KETEK MAY AFFECT YOUR ABILITY TO DRIVE OR DO DANGEROUS ACTIVITIES. LIMIT DRIVING AND OTHER DANGEROUS ACTIVITIES.
  - IF YOU HAVE VISION PROBLEMS OR FAINT WHILE TAKING KETEK
    - DO NOT DRIVE, OPERATE HEAVY MACHINES, OR DO DANGEROUS ACTIVITIES.
    - CALL YOUR DOCTOR BEFORE TAKING ANOTHER DOSE OF KETEK IF YOU HAVE VISION PROBLEMS OR FAINT.

See "What are the possible side effects of KETEK?" for other side effects of KETEK.

WHAT IS KETEK?

KETEK is an antibiotic. KETEK is used to treat adults 18 years of age and older with a lung infection called "community acquired pneumonia" that is caused by certain bacteria germs.

- KETEK is not for other types of infections caused by bacteria
- KETEK, like other antibiotics, does not kill viruses.

### WHO SHOULD NOT TAKE KETEK?

Do not take KETEK if you:

- have myasthenia gravis
- have had side effects on the liver while taking KETEK or macrolide antibiotics.
- have ever had an allergic reaction to KETEK or macrolide antibiotics.
- take cisapride (Propulsid<sup>®</sup>) or pimozone (Orap<sup>®</sup>).

**KETEK may not be right for you. Before taking KETEK, tell your doctor about all of your medical conditions, including if you:**

- have myasthenia gravis
- have liver problems
- have (or have a family history of) a heart problem called “QTc prolongation”
- have other heart problems
- are pregnant or breastfeeding

Tell your doctor about all of the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. KETEK and other medicines may affect or interact with each other, sometimes causing serious side effects.

You should not take the following cholesterol lowering medicines while taking KETEK:

- simvastatin (Zocor<sup>®</sup>, Vytorin<sup>®</sup>)
- lovastatin (Mevacor<sup>®</sup>)
- atorvastatin (Lipitor<sup>®</sup>)

Know the medicines you take. Keep a list of your medicines with you to show your doctor or pharmacist.

Do not take other medicines with KETEK without first checking with your doctor. Your doctor will tell you if you can take other medicines with KETEK.

### HOW SHOULD I TAKE KETEK?

- Take KETEK exactly as your doctor tells you. Skipping doses or not taking all of an antibiotic may:
  - make the treatment not work as well
  - increase the chance that the bacteria will develop resistance to the antibiotic
- The usual dose is two 400 mg KETEK Tablets taken at the same time once a day for 7 to 10 days. If you have kidney disease, your doctor may prescribe a lower dose for you.
- Take KETEK with or without food.
- Swallow KETEK tablets whole.
- Call your doctor if you took too much KETEK.

### WHAT ARE THE POSSIBLE SIDE EFFECTS OF KETEK?

See “What is the most important information I should know about KETEK?” for worsening of myasthenia gravis symptoms, and serious liver, vision, and fainting side effects.

#### **Other serious side effects include:**

- **Pseudomembranous colitis** (an intestine infection). Pseudomembranous colitis can happen with most antibiotics, including KETEK. Call your doctor if you get watery diarrhea, diarrhea that does not go away, or bloody stools. You may also have stomach cramps and a fever. Pseudomembranous colitis can happen up to 2 months after you have finished your antibiotic.

The most common side effects of KETEK are nausea, headache, dizziness, vomiting, and diarrhea.

These are not all of the side effects of KETEK. Ask your doctor or pharmacist for more information.

#### HOW SHOULD I STORE KETEK?

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

#### GENERAL INFORMATION ABOUT 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 doctor or pharmacist for information about KETEK that was written for healthcare professional. This information is also available on the KETEK website at [www.KETEK.com](http://www.KETEK.com).

#### 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

#### Rx Only

Medication Guide as of February 2007

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

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