

Medication Guide
KETEK[®] (KEE tek)
(telithromycin)
Tablets

Read the Medication Guide that comes with KETEK before you start taking it and each time you get a new prescription. There may be new information. 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?

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 people with myasthenia gravis after taking KETEK, in some cases leading to death.

KETEK can cause other serious side effects, including:

- 1. Severe liver damage (hepatotoxicity).** Severe liver damage, in some cases leading to a liver transplant or death has happened in people treated with KETEK. Severe liver damage has happened during treatment, even after a few doses, or right after treatment with KETEK has ended.

Stop taking 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.

Signs of liver problems include:

- increased tiredness
- loss of appetite
- nausea
- yellowing of your skin or whites of your eyes
- dark colored urine (tea colored)
- light colored stools
- right upper belly pain
- itchy skin

Do not take KETEK if you have ever had liver problems while taking KETEK or macrolide antibiotics. Macrolide antibiotics include:

- erythromycin
- azithromycin (Zithromax[®], Zmax[®])
- clarithromycin (Biaxin[®])
- dirithromycin (Dynabac[®])

- 2. 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.
- 3. Fainting. KETEK may cause you to faint,** especially if you also have nausea, vomiting, and lightheadedness.

Do not drive, operate heavy machinery, or do other dangerous activities while taking KETEK if you have:

- vision problems
- fainting
- confusion
- seeing things that are not there (visual hallucinations)

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

4. 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 (Calan[®])
- amlodipine (Norvasc[®])
- diltiazem (Cardizem[®])
- or other medications containing these products.

See **“What are the possible 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 germs called bacteria.

- KETEK is not for other types of infections.
- KETEK does not kill viruses like the common cold.

Who should not take KETEK?

Do not take KETEK if you:

- have myasthenia gravis
- have had liver problems while taking KETEK or macrolide antibiotics.
- have ever had an allergic reaction to telithromycin in KETEK or macrolide antibiotics.
- take cisapride (Propulsid[®]) or pimozide (Orap[®]).
- take colchicine (Colcrys[®]) and have kidney or liver problems.

Talk to your doctor before taking KETEK if you have any of the conditions listed above.

What should I tell my doctor before taking KETEK?

Before taking KETEK, tell your doctor if you:

- have liver 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 nonprescription medicines, vitamins, and herbal supplements. KETEK and other medicines may affect or interact with each other, sometimes causing serious side effects.

Especially tell your doctor if you take:

- colchicine (Colcrys[®]) while you take KETEK
- certain medicines called calcium channel blockers, such as: verapamil (Calan[®]), amlodipine (Norvasc[®]), diltiazem (Cardizem[®]), or other medications containing these products while you take KETEK
- cholesterol lowering medicines; you should not take these cholesterol lowering medicines while taking KETEK:
 - simvastatin (Zocor[®], Vytarin[®])
 - lovastatin (Mevacor[®])
 - atorvastatin (Lipitor[®])

Ask your doctor if you are not sure if the medicine you take is included in the list of medicines above.

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 while taking 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
- If you have kidney disease, your doctor may prescribe a lower dose for you.
- Take KETEK with or without food.
- Swallow KETEK tablets whole.
- If you take too much KETEK, call your doctor, or go to the nearest hospital emergency room right away.

What are the possible side effects of KETEK?

See “**What is the most important information I should know about KETEK?**”

KETEK may cause serious side effects, including:

- **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
- diarrhea
- problems with taste

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 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 professionals. This information is also available on the KETEK website at 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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