



YOUR GUIDE TO KETEK

WHAT KETEK IS AND WHAT IT DOES



Anapol Schwartz | Attorneys at Law

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DISCLAIMER: This information is not intended to replace the advice of a doctor. Please use this information to help in your conversation with your doctor. This is general background information and should not be followed as medical advice. Please consult your doctor regarding all medical questions and for all medical treatment.



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WHAT IS KETEK?

The antibiotic Ketek is manufactured by Sanofi-Aventis SA and was approved for the U.S. market by the Food and Drug Administration (FDA) in April 2004.

Ketek (KEE tek) is the brand name for telithromycin tablets. Ketek is a ketolide antibiotic. Telithromycin kills certain bacteria or stops its growth. Ketek kills many of the types of bacterial infections that are found in the lungs, sinus, and throat caused by community acquired pneumonia, sinusitis, and bronchitis. Ketek will not work for colds, flu, or other viral infections and should not be prescribed for such conditions. There is no generic equivalent to Ketek.

Ketek comes in film-coated tablets that are light orange, oval, and imprinted with H3647 on one side and 400 on the other side. Each Ketek tablet contains 400 mg of the active drug, telithromycin.

What are Ketek side effects?

Report these Ketek side effects to your doctor ASAP:

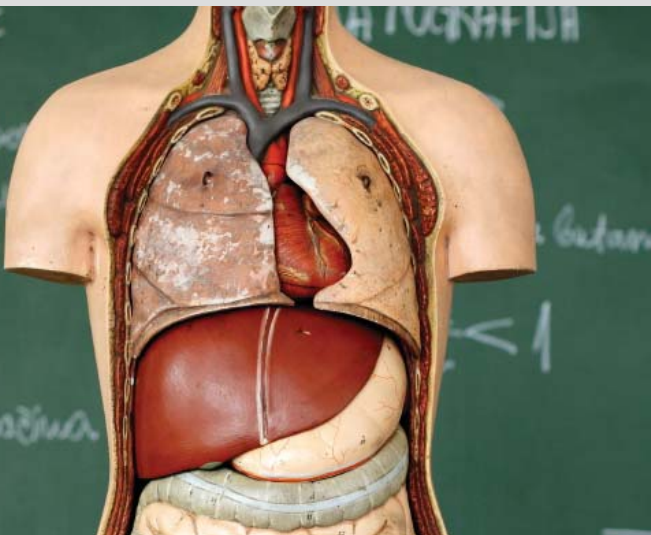
- *breathing difficulties*
- *fainting spells*
- *jaundice (yellowing of the skin and/or eyes)*
- *redness, blistering, peeling or loosening of the skin, including inside the mouth*
- *severe or watery diarrhea or persistent diarrhea*
- *skin rash, itching*
- *swelling of tongue or throat*
- *blurred vision, difficulty focusing, and double vision*
- *vomiting*





WHAT ARE KETEK POST-MARKETING ADVERSE PROBLEMS?

- **Allergic Reactions:** Face edema (facial swelling), rare reports of severe swelling below the surface of the skin and fatal systemic allergic reaction that can involve various areas of the body.
- **Cardiovascular Reactions:** fibrillation
- **Liver and bile Reactions:** Hepatic dysfunction, including increased liver enzymes, and and/or cholestatic hepatitis, with or without jaundice, has been infrequently reported with Ketek.
- **Musculoskeletal Reactions:** Muscle , rare reports of myasthenia gravis (condition in which the body's immune system fights itself causing problems with the nerves that provide communication to the muscles resulting in muscle weakness).
- **Gastrointestinal Reactions:** Abdominal distension, stomach upset, flatulence, constipation, watery bowel movements.



Questionable FDA Practices Regarding Ketek

There are two allegations regarding the circumstances about how the FDA approved Ketek for the marketplace: Questions arose about how the FDA's management instructed FDA officials to present fraudulent data to the Advisory Committee because discussing issues regarding data integrity and the conduct of a safety study would not be productive; and, did the FDA actually presenting fraudulent study data to the Advisory Committee?

About two months prior to the 2003 Advisory Committee meeting, the study site with the largest number of enrolled subjects (407) was under investigation by FDA's Office of Criminal Investigations. The FDA also inspected the second and third highest enrolling sites and found them to have similarly violated the protocol. In addition, 72 other sites raised red flags for FDA officials and investigators, including non adherence to the study protocol, which recommended between 4 and 50 study subjects per site. FDA officials also questioned how quickly more than 24,000 patients were enrolled in the study.

The FDA official charged with presenting at the Advisory Committee stated that he was not satisfied with what he knew about the integrity of a study and was against presenting it. When asked why he did indeed present a study he knew to have data integrity problems, the official replied that he was asked directly by the FDA Division Director.

The Advisory Committee members said they were not aware of the data integrity problems until July 7, 2006. Several Advisory Committee members also responded that knowledge of the data integrity problems might have affected their vote.

Ketek received a seal of approval amidst a botched and questionable study of participants who never existed.



KETEK AND LIVER DAMAGE

Ketek has been linked to hepatitis and liver damage resulting in liver transplants and death.

Hepatitis is a gastroenterological disease known as inflammation of the liver. The clinical signs and prognosis, as well as the therapy, depend on the cause. Hepatitis is characterized by fatigue, malaise, joint aches, abdominal pain, vomiting two or three times a day for the first five days, loss of appetite, dark urine, fever, jaundice, and an enlarged liver. Some chronic forms of hepatitis show very few of these signs and only when the longstanding inflammation has led to the replacement of liver cells by connective tissue resulting in cirrhosis. Certain liver function tests can also indicate hepatitis.

Ketek has been linked to liver failure.

Liver failure is categorized depending on the rapidity of onset. Acute liver failure develops rapidly, but chronic liver failure may take months or years to develop. By definition, liver failure occurs when the liver is so diseased and functioning so poorly, that brain damage is evident. Any progressive liver disease can result in liver failure.

Some liver related problems:

- Patient #1 died from liver failure only two weeks after taking Ketek for five days.
- Patient #2 required a liver transplant after using Ketek.
- Patient #3 developed drug-induced hepatitis after taking Ketek but later recovered.

Liver failure treatment involves correcting any underlying cause, if possible. Even when the cause is identified and treated, the progression to complete liver failure may be irreversible. In this case, steps are taken to slow down the decline of liver function. Liver transplantation is the definitive treatment for liver failure, but is not an option for all patients and the supply of livers is severely limited. Some medication may be given to relieve the symptoms of liver failure.





FILING KETEK LAWSUITS: HIRING A LAWYER

If you or a loved one has developed Ketek acute liver injury, Ketek induced hepatitis, need a liver transplant, or a loved one has died – consider retaining a lawyer and filing a Ketek lawsuit. As with all cases of negligence and product liability, you can consult a lawyer regarding filing a Ketek lawsuit, in order to obtain compensation.

What law firms and lawyers handle Ketek lawsuits?

Anapol Schwartz law firm is devoted to Ketek lawsuit cases. With over 30 years experience in fighting for what is just and fair, Anapol Schwartz has doggedly pursued the mega-million pharmaceutical corporations on behalf of people just like you. They have a track record to be proud of.

The likelihood of a successful Ketek antibiotic lawsuit varies based on the facts of each case. The circumstances of each person's use of Ketek will vary and will affect the outcome of any Ketek lawsuit. There are also local issues, involving specific State laws, which may alter the handling of each Ketek lawsuit.

Anapol Schwartz has offices in Pennsylvania – Philadelphia, Harrisburg, Media, and Reading; and Cherry Hill, New Jersey.

How much does a Ketek lawsuit cost?

Anapol Schwartz's services are on a contingency-fee basis which means if you don't win your Ketek lawsuit, you don't pay for our legal services.

Who are the Ketek lawsuits filed against?

Grounds for Ketek lawsuit legal proceedings lie almost solely with Ketek's manufacturer, Sanofi-Aventis and its subsidiaries. This is most likely where the Ketek side effects lawsuit would be directed.



RESOURCES ON THE WEB

What is liver failure?

<http://www.clevelandclinic.org/health/health-info/docs/3300/3368.asp?index=9494>

Liver failure is a life-threatening condition that demands urgent medical care. Most of the time liver failure happens over a period of many years. But sometimes it can happen in as little as 48 hours which could be caused by taking certain medications like Ketek.

Telithromycin

<http://www.fda.gov/cder/drug/infopage/telithromycin/qa.htm>

What is telithromycin, the generic for brand name antibiotic Ketek? Here is some vital information from the FDA.

How did Ketek antibiotic ever get approved?

<http://www.anapolschwartz.com/practices/ketek/blog/Ketek-Investigation.html>

Here's a detailed overview about the pitfalls regarding the approval of the antibiotic Ketek. There were no checks and balances. There were no in-house whistle blowers. Ketek antibiotic went on the market touted as a miracle drug for people suffering from sinusitis, pneumonia, and bronchitis.

Why does it take so long to change the label for ketek telithromycin?

<http://www.fda.gov/cder/drug/infopage/telithromycin/default.htm>

Why did it take almost nine months? How many people experienced liver toxicity during that time? Who calls the shots, the pharmaceutical company or the FDA?

Why Retain a Ketek Lawyer

<http://www.anapolschwartz.com/practices/ketek/benefits.asp>

The right ketek lawyer will make you feel taken care of. After all, you need support and the right ketek lawyers can help you and your family when you need it most. For a no-obligation, confidential consultation, please contact us to find out if we are the ketek lawyers for you.

DETERMINE YOUR LEGAL OPTIONS FOR A KETEK LAWSUIT

If you are currently taking or have taken the antibiotic Ketek, you may be suffering from serious liver damage or liver failure. Does a family member need a liver transplant after being prescribed Ketek? Or has a family member or loved one died from taking Ketek?

Please [contact a Ketek lawyer](#) for your free NO-OBLIGATION evaluation; you or your family may be eligible for a Ketek lawsuit.

How can we help you?





Anapol Schwartz | Attorneys at Law

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