

FYI (National): ANSWERS TO QUESTIONS ABOUT RILUTEK® (RILUZOLE) TABLETS

NOW THAT YOU AND YOUR PHYSICIAN HAVE CHOSEN RILUTEK (RILUZOLE) TABLETS...

....you may have some questions about your treatment. This document is designed to answer the most common questions that people with ALS have about taking Rilutek (pronounced rill-u-tek). It's still very important to tell your doctor or pharmacist if you are unsure about anything regarding Rilutek and to ask them any questions you may have about your treatment.

What is ALS?

ALS stands for Amyotrophic Lateral Sclerosis, and it is a disease of the central nervous system that affects a person's ability to move certain muscles. The central nervous system is like a complex telephone network that channels the messages from the brain to the rest of the body. These messages are carried by nerve cells called motor neurons. These motor neurons not only carry the messages, they do the "talking" for the brain and tell the muscles what to do. ALS makes it difficult for messages to get through the muscles.

What are Rilutek Tablets?

Rilutek is the first effective treatment for people with ALS. Laboratory studies suggest that Rilutek is "neuroprotective" which means it protects nerve cells from damage.

I take a lot of vitamins and antioxidants. I'm glad to know that one of the pills I take for ALS has been proven effective, and that one being Rilutek.

— Ted Heinz, ALS Patient

Many researchers believe that Rilutek protects the nerve cells by what they describe as "glutamate (pronounced glue-tah-mate) inhibition," which is explained below.

Researchers also believe that this activity could explain the effect Rilutek has on the survival of people with ALS.

How do Rilutek (riluzole) Tablets work?

The human body naturally produces a substance called glutamate. Glutamate carries signals to the motor neurons. This is one link in the chain of how the brain tells the muscles what to do. One of several theories researchers have is that in people with ALS, parts of the nervous system are overexposed to glutamate. A buildup of glutamate has been seen early in the progression of this disease. Too much glutamate "burns out" the motor neurons so that they cannot carry the brain's messages to the muscles to tell them what to do. Although researchers don't fully understand how Rilutek works, one explanation is that Rilutek may protect nerve cells from overexposure to glutamate.

What is Rilutek made of?

The active ingredient in Rilutek is riluzole (pronounced rill-you-zole). Rhone-Poulenc Rorer Pharmaceuticals Inc. is the company that makes Rilutek.

What will Rilutek do for me?

Over 1,100 patients participated in clinical trials for Rilutek. During the first year of treatment, patients who took Rilutek had a better chance of staying alive compared to patients who took a placebo (sugar pill). However, by the end of 18 months, there was no difference between the Rilutek group and those on placebo. Rilutek is not a cure for ALS, and it cannot give back function that is already lost.

When should I take Rilutek?

The recommended dose is one 50-mg Rilutek tablet every 12 hours. You should take Rilutek on a regular basis and at the same time of the day (e.g., in the morning and evening) every day, at least 1 hour before or 2 hours after a meal. It is very important that you take Rilutek as prescribed. The benefit of Rilutek can only be realized by maintaining a consistent dosing schedule. **Taking your medication every day is a key to successful therapy.**

What should I do if I miss a dose of Rilutek?

If you miss or skip a dose of Rilutek, do not take any extra tablets to make up for those you missed, but take your prescribed dose at the next regularly scheduled time.

“I will not surrender my faith, my hope, my love, and my courage to this disease. I have a lot to live for.”

—Debbie Tope, an ALS Patient

What can happen if I take more Rilutek (riluzole) Tablets than prescribed by my doctor?

There is no benefit in increasing the dose of Rilutek about two tablets per day. On the contrary, you may encounter more side effects. In case of an overdose, seek medical attention.

What about side effects of Rilutek?

Medicines can sometimes cause unwanted effects known as side effects. The *most common side effects* of Rilutek are weakness, nausea, lung function decrease*, a mild liver disorder that is typically temporary, and headache. If any side effects become troublesome, contact your doctor. Although not a side effect of Rilutek, call your doctor if you have a fever; your doctor may need to check your white blood cell count.

*not associated with a reduction in vital capacity.

Can I drive or use machines when taking Rilutek?

Rilutek may cause you to feel dizzy, have vertigo (light-headedness), or feel sleepy. If you do have these sensations, you should NOT drive a vehicle or use machinery.

Can I take other medicines while taking Rilutek?

Since it is always possible that one drug will react with another, before you take any medicines, you need to talk to your doctor. Be sure to tell your doctor and pharmacist about all other medicines you are taking, including nonprescription products and vitamins. Also, if you have to go another doctor, dentist, or hospital for any reason, remember to tell the doctor or medical professional about all the medications you are taking, including Rilutek.

Can I combine Rilutek with other investigational drugs for ALS?

Several other drugs are now under investigation for the treatment of ALS. There is no information currently available on the combination of Rilutek with these investigational drugs. You should discuss this with your doctor.

How long should I take Rilutek (riluzole) Tablets?

This decision should be made with your doctor. In clinical trials, Rilutek was shown to be safe during 18 months of continuous treatment. In follow-up studies, patients continued to take Rilutek for almost 5 years.

If I stop taking Rilutek, what impact will this have on my condition?

There appear to be no side effects if you stop Rilutek. However, researchers do not know if the effects of Rilutek are continued after treatment is stopped.

Is there anything I should avoid?

Of course, it is generally not recommended that you smoke or drink excessive amounts of alcohol. But this is particularly important for patients taking Rilutek. Smoking may decrease the amount of Rilutek in the blood; alcohol may contribute to compromising liver function and may be associated with an increased risk of liver problems with Rilutek.

Are there any other considerations?

Before you take Rilutek, it is important to tell your doctor if you have liver or kidney problems. While you are using Rilutek, it is recommended that you have a blood test from time to time. These tests are important because some people experience a mild liver disorder that is typically temporary. Depending on these test results, additional evaluation by your doctor may be required. Also, call your doctor if you have a fever. If you have an allergic reaction to Rilutek, call your doctor immediately. If you are pregnant, suspect you are pregnant, or are planning on becoming pregnant, you should not use Rilutek without first discussing it with your doctor. Also, if you are breastfeeding or you plan to breast-feed, you should discuss this with your doctor before taking Rilutek. Remember to store Rilutek at room temperature (68° 77°F) and protect it from bright light. Be sure to keep Rilutek out of reach of children.