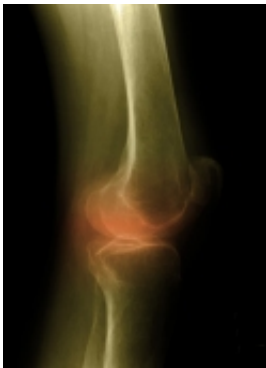


## Arthritis treatment linked to liver problems in study

June 18 2012, By Randy Dotinga, HealthDay Reporter

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But it's unclear why 'medical food' called Limbrel might make patients sick.

(HealthDay) -- A "medical food" called Limbrel, which doctors prescribe to treat osteoarthritis of the knee, was linked to several cases of liver disease in a small study, but the effects so far seem to be rare and easily reversible.

Still, patients who take Limbrel, also known as flavocoxid, should be aware of the potential for liver problems, said study lead author Dr. Naga Chalasani, director of the division of gastroenterology and hepatology at Indiana University School of Medicine, in Indianapolis.

Patients should not assume that "medical foods," such as Limbrel, are 100 percent safe, he added.

In the United States, medical foods are not subjected to the clinical trials required of prescription drugs before coming to market.

According to Primus Pharmaceuticals, Inc., maker of Limbrel, the main ingredients of the pills are plant elements known as bioflavonoids, specifically baicalin and catechins. The company says Limbrel helps improve mobility and relieve joint discomfort and stiffness related to [arthritis](#).

For the new study, Chalasani and colleagues analyzed 877 cases of liver injury and found four linked with Limbrel. The researchers said it's "highly likely" that the product caused the liver problems in three of the patients and possible in the other one.

Symptoms included nausea, fatigue and yellow skin, Chalasani said. The four patients were women between 57 and 68 years old who showed signs of liver illness between one and three months after taking Limbrel.

They recovered within weeks of discontinuing the drug.

"Our report provides convincing evidence that flavocoxid is capable of causing clinically apparent, acute [liver injury](#)," the study authors wrote. They also noted that the pharmaceutical company has discovered 31 possible cases of liver problems among more than 284,000 users since the drug was brought to market in 2004.

It's not clear why Limbrel might cause [liver problems](#), although the researchers suspect one of its chemicals may be at fault, Chalasani said.

According to Dr. Robert Levy, director of clinical development for Primus Pharmaceuticals, "Limbrel is, by far, the safest anti-inflammatory on the market."

Limbrel has an "extraordinary safety profile," he added. He said medical foods must be prescribed and used under the direction of a physician, adding that physicians should monitor the livers of patients who take the drugs.

"Because the liver is the site of metabolism of most drugs and foreign chemicals, a great many drugs, including all anti-inflammatory agents, are known to have some liver toxicity," Levy said.

Painkillers, another common treatment for [osteoarthritis](#), only provide limited relief and are also associated with adverse events, the study authors said.

About 20 million Americans suffer from osteoarthritis, which is the leading cause of disability in the United States, according to the U.S. National Institutes of Health.

Study lead author Chalasani said patients and physicians should be aware that medical food products haven't gone through the same kind of review as regular [prescription drugs](#).

"I'll bet most people who prescribe Limbrel think it's gone through the typical review process," he said. "If a physician chooses to prescribe Limbrel, he or she should be aware that it can cause this toxicity." If patients develop symptoms of liver damage, they should stop taking Limbrel, he added.

The study appears in the June 19 issue of the *Annals of Internal Medicine*.

The authors of an accompanying journal editorial said that the current policy of allowing medical foods to come to market without rigorous testing may need to be reconsidered, given their popularity and potential

for damage.

**More information:** The U.S. Food and Drug Administration has more about [medical foods](#).

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