

PSORIATIC ARTHRITIS NEWS AND VIEWS

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PSORIATIC ARTHRITIS MEDICAL NEWS

ARTHRITIS BETTER WITH DIET & EXERCISE

A study involved 252 randomized participants, all age 60 or older, who were overweight, sedentary and had knee pain or knee osteoarthritis. The participants were divided into one of four groups: exercise only, dietary weight loss only, dietary weight loss plus exercise, and the control group called healthy lifestyle. Participants in an 18-month program of exercise and calorie-restricted diet had a 24 percent improvement in physical function. Participants in this group also reported the most significant improvements in knee pain -- a decrease of more than 30 percent.

Quote: "We suggest that the combination of diet plus exercise produces consistently better and clinically relevant improvements in physical function compared with diet or exercise alone." (Stephen Messier, lead researcher, Wake Forest University)

Comment: For anyone with arthritis, a diet and exercise program should be approved by a physician, lest it do more harm than good.

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WEIGHT LOSS, EXERCISE COMBINATION EFFECTIVE ARTHRITIS TREATMENT By Sarah Mansell May 2004

A combination of moderate weight loss and exercise is an effective treatment for overweight adults with osteoarthritis of the knee, according to new research from Wake Forest University published in the May issue of the journal *Arthritis & Rheumatism*.

"Considering that side effects often limit the use of drug therapy and surgical intervention is often ineffective for mild or moderate knee osteoarthritis, our results give strong support to the combination of exercise and weight loss as a cornerstone for the treatment of overweight osteoarthritis patients," said Stephen Messier, professor of health and exercise science and principal investigator of the study.

Researchers from Wake Forest's health and exercise science department and Wake Forest University Baptist Medical Center teamed for the study, called ADAPT

(Arthritis, Diet and Activity Promotion Trial). They found that participants in an 18-month program of exercise and calorie-restricted diet had a 24 percent improvement in physical function. Participants in this group also reported the most significant improvements in knee pain -- a decrease of more than 30

percent.

“Our study supports modest weight loss and moderate exercise as a safe, effective therapy for osteoarthritis of the knee,” said Dr. Marco Pahor, professor of gerontology in the Wake Forest School of Medicine at Wake Forest Baptist Medical Center and a co-researcher on the study. Pahor is director of the Claude D. Pepper Older Americans Independence Center of Wake Forest University.

Arthritis is the leading cause of physical disability in adults, affecting more than 70 million Americans. Marked by joint damage and chronic pain, osteoarthritis is the most common form of arthritis. Messier said problems with current treatments—anti-inflammatory drugs with potentially serious long-term side effects and surgery that can be ineffective—present a need for an alternative therapy.

ADAPT measured improvement in physical function, pain and mobility in 252 randomized participants, all age 60 or older, who were overweight, sedentary and

had knee pain or knee osteoarthritis. The participants were divided into one of four groups: exercise only, dietary weight loss only, dietary weight loss plus exercise, and the control group called healthy lifestyle.

The exercise group did aerobic and resistance activities for one hour, three times a week. The diet group attended regular meetings on changing their eating habits and reducing calories in their diets. The combination group, where

the most improvement was measured, participated in both programs. The healthy lifestyle group attended classes on weight loss and exercise, but did not participate in the programs.

“We suggest that the combination of diet plus exercise produces consistently better and clinically relevant improvements in physical function compared with diet or exercise alone,” Messier said.

ADAPT was paid for by a grant from the National Institute of Aging as part of the Pepper Center of Wake Forest University. Source: Wake Forest University press release.

CDC: ARTHRITIS RAMPANT, GROWING, AND COSTLY
By Amanda Gardner - HealthDay Reporter (HealthDayNews)

One in every four U.S. adults has doctor-diagnosed arthritis, and the problem is only likely to get bigger as baby boomers age and as Americans get fatter, new government figures show.

In 1997, the last year for which numbers were available, the costs for this disease totaled \$86.2 billion -- a staggering 1 percent of the U.S. gross domestic product.

"The money used to treat arthritis and from lost earnings is equivalent to a chronic recession," said Louise Murphy, an epidemiologist under contract to the U.S. Centers for Disease Control and Prevention and one of the authors of

new findings published in the May 14 edition of the CDC publication Morbidity and Mortality Weekly Report.

The report is the first to look at arthritis prevalence state by state; in all, 30 states were examined.

According to the CDC, 49 million American adults reported doctor-diagnosed arthritis in 2001, while another 21 million reported chronic joint symptoms (CJS).

"It's an enormous problem," said Kevin Brennan, senior vice president of health policy at the Arthritis Foundation in Washington, D.C. "People with arthritis still die 10 years sooner than someone who does not have arthritis. We have a lot of work to do."

Arthritis is the leading cause of physical disability in the United States. Although there are more than 100 different types of arthritis, the most common is osteoarthritis, which is associated with aging, obesity and physical trauma to the joints.

Women and older adults are more likely to suffer from osteoarthritis. However, the condition can be largely prevented and treated.

"There is a lot of self-help things people can do for that -- exercise programs, aquatic exercise to take stress off joints, trying to lose weight, strengthening the muscles, and there are medicines that you can take for that type of pain," said Dr. Leonard Serebro, senior staff rheumatologist at the Ochsner Clinic Foundation in New Orleans.

Whether Americans are actually doing these things is another story.

The study authors looked at responses to questions about arthritis that were included in the Behavioral Risk Factor Surveillance System (BRFSS) from 30 states.

Participants, reached in a random telephone survey, were asked, "Have you ever been told by a doctor or other health professional that you have some form of arthritis, rheumatoid arthritis, gout, systemic lupus, or fibromyalgia?" Those who answered yes were considered to have doctor-diagnosed arthritis.

Doctor-diagnosed arthritis carries more weight than self-reported arthritis, Serebro pointed out.

The prevalence of doctor-diagnosed arthritis ranged from 17.8 percent in Hawaii to 35.8 percent in Alabama. The median was 27.6 percent. Older people and women were more likely to have arthritis in all states.

Possible arthritis, meaning self-reported arthritis not diagnosed by a doctor, ranged from 10.3 percent in Hawaii to 21.3 percent in Iowa, with a median of 17.3 percent.

Wyoming had the lowest arthritis-related costs (\$121 million), while

California had the highest (\$8.3 billion).

Future trends could go either way, depending on how well Americans take care of themselves. On the one hand, said Dr. Chad Helmick, one of the study authors and a medical epidemiologist with the Arthritis Program, "the population is getting older and we also have an obesity epidemic occurring." Both of those factors mean a higher risk for osteoarthritis.

On the other hand, Helmick added, "people can change their behavior to be physically active and to be a healthy weight."

"There are known interventions and they are underutilized," Brennan pointed out. "We're still not reaching enough people with an important awareness message. We're not getting enough folks diagnosed and aggressively treated."

SOURCES: Kevin Brennan, senior vice president, health policy, Arthritis Foundation, Washington, D.C.; Chad Helmick, M.D., medical epidemiologist, Arthritis Program, U.S. Centers for Disease Control and Prevention, Atlanta; Louise Murphy, epidemiologist, Arthritis Program, U.S. Centers for Disease Control and Prevention, Atlanta; Leonard Serebro, M.D., senior staff rheumatologist, Ochsner Clinic Foundation, New Orleans; May 14, 2004, Morbidity and Mortality Weekly Report
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CHOLESTEROL DRUG TO BE SOLD WITHOUT PRESCRIPTION IN BRITAIN
LONDON (AP) -- In a bid to prevent heart attacks and strokes, Britain will be the first country to permit nonprescription sales of a cholesterol-busting drug, the government said Wednesday.

The British Heart Foundation welcomed the decision, but other experts said people taking such drugs needed supervision and assessments of risks.

Health officials said a low-dose version of simvastatin, marketed as Zocor by Merck and Co. of Mount Laurel, New Jersey, would be available without a prescription at pharmacies across the country starting later this year. No date was announced.

Simvastatin belongs to a class of drugs called statins, considered a powerful weapon against the buildup of fat deposits that clogs arteries, leading to heart attacks and strokes.

"This new move will allow more people to protect themselves from the risk of coronary heart disease and heart attacks," said Health Secretary John Reid. "By extending access to this drug we are giving people more choice about how they protect their health. We are committed to extending choice whenever advised it is safe to do so."

Pharmacists will ask people a series of questions and, if needed, will offer a range of optional health tests to ensure it is safe to take the drug, Reid

added.

The Royal College of General Practitioners and the British Medical Association raised concerns.

"We are concerned that there won't have been a sufficiently thorough risk assessment before the drug is purchased," said Dr. John Chisholm, chairman of the British Medical Association's general practitioner committee. Patients on statins should be regularly monitored to assess the effectiveness of the treatment, he added.

"For those patients who do need to take statins," he said, "the low dosage available over the counter may not be enough to reduce cholesterol to safe levels."

Also, pharmacists will come under pressure to assess heart disease risk in people without having access to their medical records, other experts worried.

The drug may be sold to people who do not need it, said Dr. Jim Kennedy of the Royal College of General Practitioners.

"The risk of the drug may then outweigh the benefits," he said.

Side effects are usually mild and temporary, and mostly involving muscle aches and headache.

The British Heart Foundation, which funded one of the key studies establishing the benefits of statins, welcomed the move.

"The evidence is that, in people at risk of heart attack and stroke, taking 10 milligrams of simvastatin each night can reduce their risk by about 27 percent," said Sir Charles George, medical director of the foundation.

Under current guidelines, doctors can prescribe statins for those patients who have a 30 percent chance of having a heart attack in the next 10 years.

Johnson & Johnson.MSD, a British joint venture of Johnson & Johnson and Merck's U.K. subsidiary Merck, Sharpe and Dohme Ltd., will produce the over-the-counter version of simvastatin.

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DRUG MAKERS PROPOSE OTC CHOLESTEROL DRUGS May 14, 2004 WHITEHOUSE STATION, N.J. (AP)

Some of the world's biggest drug companies are working behind the scenes to convince regulators to let older cholesterol-lowering drugs be sold without a prescription in low doses, as Britain has just done.

A decision is months away, but approval by the Food and Drug Administration could significantly affect the nation's biggest public health problem, heart disease, and greatly expand sales in the top-selling drug category.

Cholesterol drugs, or statins, raked in \$26 billion worldwide -- \$14 billion in this country alone -- last year, according to health data company IMS Health. By limiting buildup of artery-clogging fat deposits, they can reduce risk of heart attack by about one-third. The category is dominated by blockbusters Lipitor, made by Pfizer Inc., and Zocor, made by Merck & Co. of Whitehouse Station.

While doctors say the drugs are safe, less than one-half of Americans who could benefit take them, mostly those at highest risk of heart disease, other complications and death, experts say. Most of the 18 million at moderate risk, defined as having a 10 percent to 20 percent risk of such problems over the next decade, are not on medication.

"What we're proposing with over the counter is, let's treat that 10 to 20 percent (group)," said Jerry B. Hansen, vice president of marketing for Johnson & Johnson-Merck Consumer Pharmaceuticals Company, a joint venture seeking FDA approval for a low-dose, nonprescription version of Merck's Mevacor, the first statin drug.

The added publicity also could drive more people at high risk to their doctors.

Hemant Shah, an independent pharmaceutical analyst with HKS & Co. in Warren, N.J., expects it would significantly expand statin use by people at mild to moderate risk without stealing sales from newer cholesterol drugs such as Lipitor, Zocor and AstraZeneca's Crestor, because they are much more powerful and will be used by higher-risk patients.

But Dr. Sidney Smith, past president of the American Heart Association, worries that some patients will not see a doctor regularly and address all their risk factors, including high blood pressure, smoking, diabetes, diet, exercise level and weight.

"There's a possibility that people might assume that by taking a statin they've done all they need to do," Smith said.

Dr. James Cleeman, coordinator of the National Cholesterol Education Program, has similar concerns. Although the program's 2001 update of treatment guidelines indicates more people than before should take statins, it still stresses a healthier lifestyle.

"The drugs can be potentially life-saving, but the lifestyle changes are crucial," he said.

Heart disease is the nation's No. 1 killer, claiming nearly 1 million lives each year. Still, allowing nonprescription sales would be quite a departure for a drug category where periodic follow-up testing is the norm.

British health officials on Wednesday approved the world's first nonprescription cholesterol drug, saying Zocor can be sold without a prescription at

pharmacies later this year. There, however, consumers will ask a pharmacist for the drug and answer questions to determine whether it is appropriate.

Merck and J&J plan to file for FDA approval by year's end, Ed Hemwall, vice president of global regulatory and scientific affairs for the J&J-Merck operation, told The Associated Press.

Meanwhile, New York-based Bristol-Myers Squibb Co. wants to sell a nonprescription version of Pravachol, its top seller, which loses patent protection in 2006, said spokeswoman Julie Keenan.

FDA turned down the joint venture and Bristol-Myers when they tried in 2000, but their chances look better now.

"The FDA has an open mind, as it were, regarding the issue," said Dr. David Orloff, of the agency's Center for Drug Evaluation and Research. He noted that FDA rescinded a 2000 statement opposing the idea.

Shah, of HKS, gives approval a 50-50 chance.

In recent years, FDA has approved nonprescription forms of antihistamine Claritin, Prilosec, Pepcid and Tagamet for severe heartburn, and several products for migraine headaches.

Merck and J&J set up their joint venture in 1989 to market Merck prescription drugs going off patent, such as Pepcid, after getting nonprescription approval. A Mevacor switch would be their second success.

Besides compiling evidence of Mevacor's safety and effectiveness, the venture has worked with nearly 10,000 consumers through surveys, focus groups and tests in mock pharmacies. It's all aimed at proving to FDA that the average Joe could correctly follow the proposed package information to determine whether he is a good candidate for the nonprescription version or needs a much stronger prescription dose.

"Visits with a doctor are not required but are highly encouraged," under the application being prepared for FDA, Hemwall said.

The company would encourage people to get follow-up tests of cholesterol levels. Hemwall said it will ask FDA not to require tests of liver function, because early concerns have proven since unwarranted.

Merck says nonprescription Mevacor likely will cost about \$1 for each daily 20-milligram pill -- more than what many insurance companies would charge for a co-payment on a brand-name prescription drug. Prescription Mevacor currently costs \$2.10 per pill.

Launched in 1987, it had peak sales of \$1.3 billion in 1994. That dropped to \$31 million last year amid competition from generics and heavily advertised Lipitor. Copyright 2004 the Associated Press. All rights reserved

CHRONIC PAIN - SUFFERED IN SILENCE

We all know people who suffer pain in silence, for example, acquaintances who refuse to take analgesics for occasional headaches. It appears, however, that people who suffer from a worse type of pain -- chronic pain -- are more likely to suffer in silence, denying pain, delaying visits to doctors, and refusing treatment. Chronic pain is a complex issue, and it is not clear why individuals would not do everything possible to reduce the pain. A simple survey such as the one reported here does not even begin to provide an understanding of chronic pain and individuals' responses to it. What it does is reinforce what we already know, specifically, that chronic pain is a widespread and costly condition.

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CHRONIC PAIN SUFFERERS SUFFER IN SILENCE By Amanda Gardner HealthDay Reporter (HealthDayNews)

Rachel Bevins has been in pain since 1996. At first, the pain was intermittent; for the past three years, it has been unrelenting.

"Pain is just a part of me, just like I have brown hair and I weigh so many pounds," said Bevins, 32, who suffers from fibromyalgia. "I have pain. That's just a normal part of my life."

According to a new survey released Thursday from the American Chronic Pain Association, Bevins' attitude is also normal, at least among pain sufferers.

The Americans Living with Pain Survey canvassed 800 people suffering from chronic pain and found they often denied the pain, delayed seeing a doctor and, when they did seek medical help, tended to shy away from treatment.

Almost a third of Americans experience chronic pain at some point in their lives, said a recent report from the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the National Pharmaceutical Council.

At any particular point in time, about 50 million Americans suffer from persistent pain. Chronic pain is the No. 1 cause of adult disability and represents about \$100 billion in lost productivity each year, according to the report.

The pain survey, which was supported by Endo Pharmaceuticals, found 72 percent of people with chronic pain have lived with it for more than three years, while a third have lived with it for more than a decade. At the same time, 44 percent of those who have talked to their doctor about the pain delayed doing so. Slightly more than half (53 percent) of those who eventually visit their doctor do so because their pain is getting worse.

Despite this apparent reluctance to see a health-care professional, the majority of those surveyed admitted pain had a major impact on their lives, including 82 percent of young people who said they were affected emotionally by the

pain.

One in six said it had adversely affected their careers.

Almost half (45 percent) said it had negatively impacted their personal relationships.

And 51 percent of those employed said it had affected their productivity; 61 percent said it affected their daily routine, and 27 percent said it affected their ability to actually get to work.

For Bevins, who lives in Newport News, Va., chronic pain has meant giving up some of her most precious dreams and completely overhauling her life to accommodate it.

She has had to give up her dream of being a professional dancer. And she has had to stop working as a public school teacher because, she said, "I'm not dependable as far as times go. There are days that I wake up and can hardly get out bed, and then there are days where my mornings may be fine but then my afternoons I'm totally wiped out."

And although she and her husband, Brian, are keeping their fingers crossed, they have had to shelve their plans for having a baby, at least for the time being.

Bevins has wanted to be a mom since she was 16, but she's worried that all the medications she takes would affect the baby and that being pregnant might take too much of a toll on her body. She also worries about having the energy to care for an infant.

Then there are the daily hardships. She can no longer keep house, and she frets about not being able to cook.

"I hate not being able to have quality food," she said. She did, however, "swallow her pride" and now uses the electric buggy when shopping for groceries.

Penney Cowan, executive director of the American Chronic Pain Association, who also lives with chronic pain, hopes the survey will help people understand how pain impacts so many lives in so many ways. She also hopes it will persuade more pain sufferers to take an active role in their own treatment.

"Ideally, we want them to begin to make the transition from the mindset of a patient to that of a person who does not allow pain to become their identity so they can eventually cope with it," she said.

"There is hope," Bevins added. "You can end up accepting your pain as just another part of you. It's just something that's there. It doesn't mean your dreams have to stop. They may have to be altered."

SOURCES: Rachel Bevins, Newport News, Va.; Penney Cowan, executive director, American Chronic Pain Association, Rockland, Calif.; Pain: Current Understanding of Assessment, Management, and Treatments
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COX-2 INHIBITOR COULD BE SAFEST ANTI-INFLAMMATORY DRUG FOR OLDER PEOPLE

May
28, 2004 (The Lancet)

A Canadian study involving over 130,000 older people in this week's issue of THE LANCET shows how the anti-inflammatory cyclo-oxygenase-2 (COX-2) inhibitor celecoxib may have a lower risk of congestive heart failure compared with other non-steroidal anti-inflammatory drugs.

Non-selective, non-steroidal anti-inflammatory drugs (NSAIDs) are commonly used by older people to relieve arthritis symptoms, but are associated with an increased risk of congestive heart failure. Less is known about the cardiovascular effects of COX-2 inhibitors, a newer group of NSAIDs.

Muhammad Mamdani from the Institute for Clinical Evaluative Sciences (ICES), Toronto, Canada, and colleagues assessed retrospectively the risk of hospital admission for heart failure for around 14,500 people using the COX-2 inhibitor rofecoxib, around 19,000 using the COX-2 inhibitor celecoxib, and around 5400 people who had been using non-selective NSAIDs. 100,000 people not using NSAIDs were used as a control group.

Compared with non-NSAID users, patients on rofecoxib had an 80% increase in hospital admission for heart failure; people using non-selective NSAIDs had a 40% increased admission risk. However, users of celecoxib had the same rate of hospital admission for heart failure as people who had never used NSAIDs.

Dr Mamdani comments: "our findings suggest significant differences between non-selective NSAIDs and individual COX-2 inhibitors with respect to risk of admission for congestive heart failure. The clinical relevance of these findings, in view of the widespread use of the drugs, warrants the implementation of large-scale randomized controlled trials to examine this issue further".

PATIENTS, DOCTORS, UNAWARE OF CT RADIATION DOSE

By Will Boggs, MD - Radiology, May 2004

NEW YORK (Reuters Health) - How much radiation do you get from a CT scan? It's substantially higher than most patients, and even their doctors, realize, according to a new report.

The radiation dose from one abdominal CT scan has been estimated to be equivalent to 100 to 250 chest X-rays, the authors explain in the May issue of Radiology. One controversial study has attributed 2500 deaths annually to CT examinations in the United States.

Dr. Howard P. Forman and colleagues from Yale University in New Haven, Connecticut, surveyed patients, emergency department (ED) physicians, and radiologists to determine the awareness level concerning radiation dose and possible risks associated with CT scans.

Only 5 of 76 patients (7 percent) reported being informed of the risks and

benefits before their CT scan, the authors report, and only 10 of 45 ED physicians (22 percent) reported explaining those risks and benefits to their patients.

Nearly half the radiologists (47 percent) believed that a CT scan increased the lifetime risk of cancer, the results indicate, but a similar belief was reported by only 3 percent of patients and 9 percent of ED physicians.

Ninety-two percent of patients estimated the radiation dose of one CT scan to be no more than 10 chest X-rays, the researchers note, as did 51 percent of ED physicians and 61 percent of radiologists.

Only 22 percent of ED physicians and 13 percent of radiologists (and none of the patients) had dose estimates in the accurate range.

"Given the current debate about the possible increased cancer risk associated with diagnostic CT scans," the investigators write, "we believe that it is important that the radiology community make current information regarding CT radiation dose more widely available."

Physicians are not adequately prepared to answer questions their patients should be asking about the risks and benefits of imaging studies, Forman told Reuters Health. "We must empower our patients to ask questions, and our physicians ... must become better prepared to answer these important questions."

"Not all imaging is necessary and unnecessary imaging, with its attendant risk, is bad medicine," Forman concluded. "On the other hand, I would not want to frighten patients from having necessary studies performed; they should be informed, though."

SOURCE Radiology, May 2004. Copyright © 2004 Reuters Limited. All rights reserved.

FIRST IN NEW CLASS OF ANTIBIOTICS APPROVED FDA gives go-ahead to Ketek to fight pneumonia - The Associated Press

Doctors are about to get the first in a new class of antibiotics to treat patients with a type of drug-resistant pneumonia, as well as those with sinusitis and bronchitis.

The Food and Drug Administration approved Ketek in late May.

It's the first ketolide, a new family of antibiotics structurally similar to drugs like that old standby erythromycin but different enough to offer an alternative that could prove important for certain patients, said FDA anti-infectives chief Dr. Janice Soreth.

Doctors are eager to have another option, she said.

Dr. Paul Iannini, a Yale University professor of medicine who helped research the drug, predicted it will quickly become a first-line choice.

DRUG TO TARGET STREP BACTERIA

A type of strep bacteria that causes community-acquired pneumonia is increasingly able to overpower one or more antibiotics. About 20 percent of streptococcus pneumonia now is multi-drug-resistant, Iannini said. Newer antibiotics called fluoroquinolones have been used to treat drug-resistant strep pneumonia, but a few strains resistant to those drugs are starting to form.

Ketek not only would offer an important option for patients running out of other options, but it may prove less likely to spur germs to resist antibiotics,

Iannini said.

It has been over 70 years since the first life-saving antibiotic, penicillin, was discovered. But in recent years, inappropriate use of antibiotics has yielded these wonder drugs less and less effective. Read on to learn more about antibiotic resistance and what you can do to help prevent it.

Antibiotic resistance occurs when bacteria that cause infection are not killed by the antibiotics taken to stop the infection. Those that survive carry genes that allow them to evade the drugs intended to destroy them.

Antibiotics do not directly cause resistance but they do create an environment where the resistant strains can proliferate. Overuse of antibiotics is cited as a cause of resistance. Infections caused by resistant bacteria fail to respond to treatment, resulting in prolonged illness and increased risk of death.

Don't pressure your doctor to prescribe antibiotics for viral infections. Antibiotics battle bacteria, not viruses. According to researchers at the CDC, 50 million of the 150 million outpatient prescriptions each year are unneeded. Follow prescription instructions. Measure liquid antibiotics and take the full course for the full number of days. Underdosing, skipping doses and stopping early can encourage resistant strains to develop. Ask your doctor if a short course of antibiotics will work as well as a long one. Shorter courses give resistant bacteria less time to take over.

First, it more specifically targets bacteria in the respiratory tract than germs throughout the body; many other antibiotics are more broad-ranging.

Second, it has chemical properties that seem less likely than certain other drugs, such as erythromycin, to push a vulnerable germ into true resistance, Iannini said.

Drug-resistant pneumonia aside, Ketek is approved to treat acute bacterial sinusitis and acute flare-ups of chronic bronchitis, conditions that affect thousands of Americans. Patients would use the drug for five to 10 days, depending on the condition being treated.

In studies that compared Ketek with certain other antibiotics, the drug proved equally effective and had similar side effects, Iannini said.

While Ketek has been sold in other countries since 2001, its U.S. approval was hard-won. The FDA first raised questions about possible liver and heart side effects that same year. Closer examination eased those concerns.

Usual side effects were similar to other antibiotics, such as nausea and headache, said maker Aventis Pharmaceuticals.

SPECIAL WARNINGS

But FDA did have some special warnings:

Ketek could increase the risk of muscle damage in patients taking three common cholesterol-lowering drugs called statins — Zocor, Mevacor and Lipitor.

Users of those statins should temporarily quit the anti-cholesterol pills until they're through using Ketek, Soreth said.

Very rarely, Ketek users experienced some vision blurring. It seemed to happen more often to women under 40, and does seem to go away once the drug is stopped, Soreth said. People experiencing the side effect should avoid driving or

other hazardous activities.

Aventis said Ketek will be available, by prescription, in late July; it wouldn't disclose a price.

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Good Health to All,

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