

Vaccine to Cut Risk of Shingles in Older People Is Approved

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Published: May 27, 2006

WASHINGTON, May 26 — Federal drug regulators have approved the first vaccine intended to reduce the risk of shingles in people 60 and older.

The vaccine, called Zostavax, is a souped-up version of the chickenpox vaccine. Both chickenpox and shingles are caused by the [herpes](#) zoster [virus](#), which is present in almost everyone. The approval was announced on Friday.

Zostavax, made by Merck, works by mimicking a shingles attack, but without the pain or blisters that shingles causes. The vaccine strengthens the body's immune response against the virus, reducing the chances of an outbreak, as well as the severity of the disease if it does occur.

The science behind the vaccine is relatively simple. Zostavax is roughly equivalent to 14 doses of the pediatric chickenpox vaccine.

Nonetheless, Zostavax represents a significant breakthrough, several scientists said. It is the first therapeutic vaccine, meaning it prevents or eases the severity of the problems from an infection that has already occurred.

Scientists have been hoping to create such vaccines against [cancer](#) and [AIDS](#), but without much success.

"It's a breakthrough in that it's the first vaccine that is actually designed to keep an infection in check," said Dr. Walter Orenstein, associate director of the Emory Vaccine Center at Emory University, who has consulted for Merck.

Zostavax is also the first vaccine in 30 years that is intended exclusively for older people, and it comes in the midst of a minor surge in nonpediatric vaccines.

Last year, the [Food and Drug Administration](#) approved Menactra, a vaccine to prevent meningococcal meningitis. Menactra is generally given to teenagers. And Merck is expected to gain approval next month for a cervical cancer vaccine that is likely to become popular among teenagers and young adults.

The herpes zoster virus normally lives neutered and imprisoned in nerve cells buried near the spine. During a shingles outbreak, the body's prison guards — crucial parts of the immune system called lymphocytes — become weakened and allow the virus to escape. The result is a painful itch that usually starts at the spine and travels across the midsection on one side of the body. This pain is often followed by a belt of blisters.

Outbreaks can recur, and the virus can significantly damage nerve cells and lead to pain that can endure for months or years. Zostavax primes again the body's defenses against the virus.

There are an estimated one million new cases of shingles in the United States each year, and the risk of contracting the disease ranges from 10 percent to 30 percent over a lifetime. For those over 85, the risk hovers around 50 percent. The incidence of the disease has gradually increased for decades, perhaps because of longer lives.

About half of all cases occur in those over 60, but younger people with immune problems, AIDS or cancer also have a higher risk.

To prove Zostavax effective, Merck sponsored a trial in 38,546 people over 60 who had never had shingles. Half got the vaccine, and half received a placebo. After three years, those who did not receive Zostavax suffered twice as many shingles cases as those who did.

Perhaps just as important, those who received the vaccine and then developed shingles generally experienced less pain than those who received placebos.

"The best way to treat [chronic pain](#) is to prevent it," said Dr. Anne Louise Oaklander, an associate professor of neurology at Harvard Medical School, who described the vaccine as a landmark. "Shingles is the most common neurological disease in the country."

Merck will charge \$152.50 for the vaccine, which is administered with a single injection. Doctors will probably charge more.

Merck expects to begin shipping the vaccine "soon," the company said in a news release. But its adoption may be slow, because doctors must store the vaccine in freezers, and many geriatricians do not have freezers in their offices.

Catherine Arnold, a senior research analyst at Credit Suisse, an investment bank, estimated that Zostavax would generate \$1 billion in sales for Merck by 2010.

"But I could be biased," said Ms. Arnold, who suffered a painful case of shingles that began in September 2004 and has only recently subsided. The pain was so intense that she underwent a spinal injection of [steroids](#) and ended up taking a collection of other drugs orally.

"It was my constant foe for almost two years," she said. "I can imagine being over 60, and being in less-good health, and being really miserable."

Since Zostavax uses the same medicine as the pediatric chickenpox vaccine, it is expected to be extremely safe, Dr. Oaklander said. In tests, the vaccine caused some tenderness at the injection site and a slight increase in headaches. It is not expected to be of use in treating a shingles attack.

Submitted by Evo Alexandre