

## Malaria drug warning follows problems

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WASHINGTON, July 10 (UPI) -- The Food and Drug Administration has taken the rare step of ordering that patients are warned directly of serious mental problems and reports of suicide linked to a common anti-malaria drug called Lariam.

The move -- which the FDA has ordered only 17 times previously -- follows a decade of increasingly dire warnings about the drug, and a trail of horror stories from people who said they have suffered from side effects from the drug.

Lariam hit the news last summer after three Fort Bragg, N.C., soldiers accused of killing their wives after returning from Afghanistan appeared to have taken the drug. Two of the three shot themselves after killing their wives; the third hanged himself in his jail cell in March. A U.S. Army report said the drug was an "unlikely" factor for the cluster of deaths but did not rule it out in any one case.

The FDA on Wednesday required by law that all doctors hand patients a "medication guide" with the new Lariam warnings. It is the 18th time the FDA has made the aggressive move.

The new warnings say the drug has been associated with "serious psychiatric adverse events" that "may persist even after stopping the medication." It also notes "rare reports have claimed that Lariam users think about killing themselves" and "rarer reports of suicides."

The FDA says the guides are used for drugs "that pose a serious and significant public health concern."

"The Lariam Medication Guide is an important new tool for managing the risks of Lariam, one of the most highly effective means of combating one of the deadliest diseases in the world," FDA Commissioner Mark B. McClellan said.

Lariam's manufacturer, Roche Pharmaceuticals of Nutley, N.J., is also sending letters to U.S. doctors and pharmacists about the new guide.

Critics said the FDA move is late. "This is probably long overdue," said Larry Sasich, of Public Citizen, a government and business watchdog group. "This information should have been in people's hands years ago."

The FDA also requires that doctors hand out a medication guide warning of possible suicide risk for another Roche drug, Accutane, which is used to treat serious cases of acne.

With Lariam, Roche in May 2002 settled a lawsuit brought by an Ohio woman who claimed her husband had committed suicide after taking the drug. The terms were not disclosed.

For more than a decade, Peace Corps volunteers and U.S. travelers given Lariam have complained of frightening episodes of hallucinations, delusions and suicidal thoughts. Starting in Somalia in the early 1990s, soldiers from a series of deployments have told similar stories about the drug, saying it has also caused sudden, uncontrollable rage and homicidal urges.

Roche has placed increasingly serious warnings on the Lariam's product label, read by doctors and pharmacists, since the FDA approved it in 1989. It added in 1999 that, "Suicidal ideation has also rarely been reported, but no relationship to drug administration has been established."

Last July, the FDA updated Lariam's official product label warning of "anxiety, paranoia and depression" and "hallucinations and psychotic behavior" that "have been reported to continue long after (Lariam) has been stopped." It also said that, "Rare cases of suicidal ideation (thinking) and suicide have been reported though no relationship to drug administration has been confirmed."

Roche last September sent a letter to 120,000 doctors about those label changes.

Following the string of events at Fort Bragg last summer, the drug company told United Press International that malaria is a dangerous disease and that, "It is important to note that Lariam is not associated with violent, criminal conduct."

The FDA told UPI last September that suicide might have to be tolerated because malaria is such a deadly disease. "Suicide in one in perhaps -- I don't know -- 1 million or however many cases you can actually calculate for Lariam may have to be acceptable on the basis for the risk for malaria," said Dr. Leonard Sacks, a medical officer with the FDA.

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