

Pfizer recalls 1 million packets of US birth control pills

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US pharmaceutical giant Pfizer on Wednesday recalled one million packets of birth control pills over a packaging error that could put women at risk of unintended pregnancy.

The pills, about half of which were the brand name Lo/Ovral-28 and the other half were generic norgestrel and ethinyl estradiol tablets, may be improperly arranged so that inactive pills are taken at the wrong time in the monthly cycle.

Doctors described the recall as "very serious" and urged women who have been taking the pills to talk with their doctor and use back-up methods of protection.

A similar recall was issued in September by a different pharmaceutical company, Qualitest in Alabama, due to packaging errors that affected 1.4 million packets of birth control pills distributed in 2011.

Pfizer said its own investigation had "found that some blister packs may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence," the company said in a statement.

"As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy."

The pills were manufactured and packaged by Pfizer in New York state



and commercialized by Akrimax Rx Products under the Akrimax brand name in the United States.

Each packet is supposed to contain 21 active tablets and seven inactive pills.

"The cause of the inexact package counts has been identified and corrected," Pfizer spokeswoman Grace Ann Arnold told AFP.

She described the problem as a "mechanical and operator visual inspection systems failure on the packaging line."

Patients who have been taking the affected lot numbers, posted on the Pfizer and US Food and Drug Administration websites, should notify their physician, return the product to the pharmacy and begin using a back-up form of non-hormonal birth control right away.

"This is very, very serious," said Steven Goldstein, professor of obstetrics and gynecology at New York University Langone Medical Center. These pills "cannot be considered to be adequate contraception."

Goldstein added that the pills affected are not among the newer, lowdose pills that have risen in popularity in recent years, but may be commonly distributed by hospitals and low-cost outlets.

"It is a very old pill. It has been around for decades. There have been a number of newer, lower doses, better progestins, and it is not really marketed much anymore," he told AFP.

"A very small minority of people are probably taking this. However, anybody who is taking these packs may be at an unknown but too high of a risk for unintended pregnancy."



Gynecologist Jill Rabin at Long Island Jewish Medical Center in New York urged women who have been taking the affected pills to also get a pregnancy test.

"Sequence and content of active versus inactive pills is crucial in determining efficacy, including whether or not unwanted pregnancy will be actually prevented," she said.

"Ensure that you are not currently pregnant by taking a pregnancy test if you have any symptoms of pregnancy, such as missed periods, abnormal bleeding."

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