

French drugmaker warns on morning-after pill (Update)

November 26 2013, by Greg Keller

A French contraceptive maker said Tuesday its morning-after pill doesn't work when taken by women who weigh more than 80 kilograms (176 pounds) and plans to change its labels to warn patients.

The decision to change its labels by HRA Pharma is based on a previous study of levonorgestrel, one of the active ingredients in its Norlevo emergency contraceptive, said Frederique Welgryn, HRA Pharma's head of women's health.

Some doctors said heavy women shouldn't assume emergency contraception won't work for them and that they should talk to a health professional or consider alternatives like a copper IUD, a birth control device that can be fitted on the uterus.

Norlevo is not sold in the U.S. but another drug with the same active ingredient is widely available.

Welgryn said a dose of HRA's drug contains 1.5 mg of levonorgestrel, identical to that found in Plan B One-Step, manufactured by Teva Pharmaceuticals in the U.S. Denise Bradley, a spokeswoman for the company, declined to comment.

The Food and Drug Administration is currently reviewing the issue and will determine "what, if any, labeling changes to approved emergency contraceptives are warranted," according to spokeswoman Erica Jefferson in an email.

Welgryn said that while the results of the study conducted by the University of Edinburgh in 2011 were "quite surprising," the last few years have seen much discussion about contraceptives' efficacy in overweight or obese patients.

HRA Pharma Chief Executive Erin Gainer estimated that millions of women across Europe use emergency contraceptives identical to Norlevo. Gainer declined to give sales figures for Norlevo alone.

Anna Glasier, a lead researcher in the 2011 study, said that their research wasn't designed to look specifically at the effect of weight on emergency contraception. She said their study only included about 1,700 women.

"It is not my place to comment as to whether the company's decision to change advice is premature," she said in an email.

She also noted another previous analysis that found there was no solid evidence to show that hormonal contraceptives were less effective in overweight women, but the quality of the studies was low.

The morning-after pill contains a higher dose of the hormone in regular birth control pills. Taking it within 72 hours of rape, condom failure or just forgetting regular contraception can cut the chances of pregnancy by up to 89 percent, but it works best within the first 24 hours. If a woman is already pregnant, the pill, which prevents ovulation or fertilization of an egg, has no effect.

HRA began the process of consulting with French regulators about changing the pill's labeling in 2012 and it has taken until now for Europe's drug regulators to approve the change, Welgryn said.

The new warning also says that the drug's efficacy is reduced in women who weigh more than 75 kilograms (165 pounds), and it is ineffective in

women who weigh more than 80 kilograms.

Dr. Diana Mansour, a spokeswoman for Britain's Faculty of Sexual and Reproductive Healthcare, said in overweight and obese women the drug probably gets absorbed into their fat more quickly and doesn't have enough time to work in their bodies.

"It has less of a chance to delay ovulation and there are lower levels (in the blood) of the drug to have an effect," she said. Mansour said there wasn't enough information to know if simply giving obese women a higher dose of the drug would solve the problem.

In the U.K., doctors haven't been given any advice to stop giving overweight or obese women Levonelle, which contains the same active ingredient as Norlevo.

Lynn Hearton, clinical lead for the FPA sexual health charity, said any overweight or obese women concerned about emergency contraception should speak to a medical professional.

"It is particularly important we don't put some women off taking emergency contraception because they think it won't work anyway," she said.

She said women should consider using an IUD, which can be inserted in the womb up to five days after unprotected sex.

HRA markets Norlevo in about 50 countries worldwide. It began marketing the pill in France in 1999.

It will begin printing the warning on packaging in the first half of 2014.

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