



## Food and Drug Administration Approves Contraceptive for Continuous Use

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May 22, 2007, The Food and Drug Administration (FDA) today approved Lybrel, the first continuous use drug product for prevention of pregnancy.

The new contraceptive, Lybrel, comes in a 28 day-pill pack with low-dose combination tablets that contain 90 micrograms of a progestin, levonorgestrel, and 20 micrograms of an estrogen, ethinyl estradiol, which are active ingredients available in other approved oral contraceptives. Continuous contraception works the same way as the 21 days on-seven days off cycle. It stops the body's monthly preparation for pregnancy by lowering the production of hormones that make pregnancy possible.

Other contraceptive pill regimens have placebo or pill-free intervals lasting four to seven days that stimulate a menstrual cycle. Lybrel is designed to be taken without the placebo or pill-free time interval. Women who use Lybrel would not have a scheduled menstrual period, but will most likely have unplanned, breakthrough, unscheduled bleeding or spotting.

The safety and efficacy of Lybrel as a contraceptive method were supported by two one-year clinical studies, enrolling more than 2,400 women, ages 18 to 49. Health care professionals and patients are advised that when considering the use of Lybrel, the convenience of having no scheduled menstruation should be weighed against the inconvenience of unscheduled bleeding or spotting. The occurrence of unscheduled bleeding decreases over time in most women who continue to take Lybrel for a full year. In the primary clinical study, 59 percent of the women who took Lybrel for one year had no bleeding or spotting during the last month of the study.

Like other available oral contraceptives, Lybrel is effective for prevention of pregnancy when used as directed. The risks of using Lybrel are similar to the risks of other conventional oral contraceptives and include an increased risk of blood clots, heart attacks, and strokes. The labeling also carries a warning that cigarette smoking increases the risk of serious cardiovascular side effects from the use of combination estrogen and progestin-containing contraceptives. Birth control pills do not protect against HIV infection (AIDS) or other sexually transmitted diseases.

Because Lybrel users will eliminate their regular periods, it may be difficult for women to recognize if they have become pregnant. Women should take a pregnancy test if they believe they may be pregnant. Women should also discuss contraceptive use, and the precautions and warnings for use of the drug product, with their doctors or other health care professional.

The approval of Lybrel concludes a comprehensive review process that included expert advice from a meeting of an FDA's Reproductive Health Drugs advisory committee and an opportunity for public comment on issues regarding hormonal contraception.

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