

# Promising Drug Gives Endometriosis Patients New Hope

For women who have tried everything but still suffer from pelvic pain due to endometriosis, the debut of a new much-awaited drug is a welcomed relief. Orilissa, which became available in August, is the first treatment approved by the U.S. Food and Drug Administration for the condition in a decade — and it's got fans among medical professionals.

"It's a good option for women who have not found relief with other treatment," says Dr. Tarek Bardawil, a gynecologist at the University of Miami Health System. "It's not a magic bullet, it's not going to solve everyone's problem, but it's very promising based on strong evidence."

Endometriosis affects between as many as 10 percent of all women of reproductive age. It's a condition in which the endometrial-like tissue, similar to the tissue that lines the uterus, grows beyond outside that organ and into other places, such as the ovaries, fallopian tubes, vagina, or bowel. In rare cases, the tissue has been found in the lungs.

For many women, it can be extremely painful, especially during menstruation, sex, urination and bowel movements. In some cases, it leads to infertility. Bardawil, who sees patients with endometriosis in his practice, calls it "a debilitating disease," and it has proven to be frustrating for both patient and physician because there's no known cure. In fact, no one knows exactly why some women have it and other don't, even why some women with endometriosis suffer significantly from pain while others don't suffer pain. We do know it could run in families and the hormone estrogen tends to make it worse.

Some experts have theorized that the disorder occurs when menstrual blood flows back through the Fallopian tubes and into the pelvic cavity instead of being secreted released through the vagina. Others have speculated that areas of the abdomen may convert into the endometrial tissue or that hormones convert cells outside the uterus into a lining similar to the uterus. Still another theory is that endometrial cells are transported out of the uterus with the help of the lymphatic system.

Whatever the reason for their roaming, these rogue endometrial cells grow and thicken, then bleed as they respond to the menstrual cycle's hormonal changes — regardless of where they are in a woman's body. Over time this misplaced tissue causes inflammation, pain and pelvic adhesions inflamed. Irritation leads to pain, scars, even adhesions that bind pelvic organs together.

Thankfully, there are treatments to alleviate the condition and “in most cases women do respond to them,” Bardawil explains.

Currently, initial treatment involves both over-the-counter and prescription pain relievers as well as birth control pills and surgery. Also available are hormone-suppressing injections of Lupron (or leuprorelin), a man-made protein that decreases estrogen in women. These injections, administered every three months, put women in a temporary form of menopause and can be used for up to one year.

Bardawil also uses physical therapy and neuro-modulation, a type of therapy that changes how the brain perceives pain. However, “I have patients who don't respond to these treatments and Orilissa can help those,” he adds.

Manufactured by the drugmaker Abbvie, Orilissa is the first oral hormone suppressant for endometriosis. It works by blocking the signal that tells the ovaries to make estrogen. The drug can be used in two different dosage levels: 150 mg once a day for a year or 200 mg twice daily for six months. According to tests by its

manufacturer, the low dose reduced menstrual pain in about 45 percent of women and the higher dose reduced it in 75 percent of women.

While those figures are heartening, Bardawil cautions that, like any drug, Orilissa has side-effects. Patients may experience hot flashes, mood changes, and night sweats, all symptoms typical of menopause and peri-menopause. The most serious side effect, however, is a loss of bone density, a result of lower estrogen levels over time.

Bardawil hopes more studies will reveal how the drug works — and how bone density is affected — if prescribed for a second round. “A lot of work still needs to be done, particularly about how long often we will be able to use it after a drug holiday.”

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### ***In Their Words***

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