

Postpartum depression pill now available to women, drug maker says

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The first postpartum depression pill approved for use in the United



States is now available to women who need it, the drug's makers announced Thursday.

Sold under the name Zurzuvae, the medication can quickly ease severe <u>postpartum depression</u> and help <u>women</u> regain their emotional equilibrium following childbirth.

The medication, which is now stocked in specialty pharmacies, can also be shipped directly to patients, Biogen and Sage Therapeutics Inc. said in a <u>news release</u> Thursday.

"Having an option like Zurzuvae that can work at Day 15 and improve symptoms in as early as three days has the potential to make a profound difference in the lives of women with PPD [postpartum depression]," Dr. Kristina Deligiannidis, a professor at the Feinstein Institutes for Medical Research in New York City who has been the lead investigator on the clinical trials that led to Zurzuvae's approval, said in the company news release.

Advocates welcomed the news.

"It's critical that as a society we recognize PPD is a serious medical condition. I have witnessed the devastating impact untreated PPD can have on women, only heightened by the fact that Black and Brown women and those living in a lower socioeconomic status are disproportionately impacted," said Wendy Davis, executive director at Postpartum Support International, said in the company news release.

"PPD should not be treated as an afterthought. We need to embrace the care of women and increase access to effective care. Treatments like Zurzuvae are a signal of hope that we're one step closer to prioritizing maternal mental health."



But rapid relief for new moms who are struggling will not come cheap: The medication will cost \$15,900 per course before insurance.

Taken as a pill once a day for two weeks, Zurzuvae showed "rapid, significant and sustained" reductions in <u>depressive symptoms</u> when compared to a placebo, according to a recent study of nearly 200 women, the FDA noted when it <u>approved</u> the medication back in August.

"Postpartum depression is a serious and potentially life-threatening condition in which women experience sadness, guilt, worthlessness—even, in severe cases, thoughts of harming themselves or their child. And, because postpartum depression can disrupt the maternal-infant bond, it can also have consequences for the child's physical and emotional development," Dr. Tiffany Farchione, director of the Division of Psychiatry in the FDA's Center for Drug Evaluation and Research, said in an agency news release announcing the approval. "Having access to an oral medication will be a beneficial option for many of these women coping with extreme, and sometimes life-threatening, feelings."

As many as 1 in 8 women in the United States develops depression just before or after giving birth.

Sahar McMahon, 39, of New York City, was one of those women: She participated in the clinical trial of Zurzuvae after the birth of her second daughter. She never wanted to hurt herself, she told CNN, but she felt she "just was existing."

"There were points where my kids would be screaming. I would leave them screaming in the living room. I'd go in my room, close the door, scream into a pillow, and then I'd think, "What are we doing this for?" McMahon said. "My whole thought process was very pessimistic, and that's not who I am at all."



After taking zuranolone, "I immediately just started feeling more like me," she recalled.

Women like McMahon need more <u>treatment options</u>. "Standard of care antidepressants, while effective, take a few weeks to start to show benefit, with maximal benefit often not seen until after 8-12 weeks of treatment," Deligiannidis said.

Moreover, these pills must be taken for months or years and can have chronic side effects.

The <u>FDA approval of Zulresso</u> (brexanolone) in 2019 for postpartum depression was a breakthrough, but the drug has to be delivered via a 60-hour intravenous infusion in a health care setting.

"There have been barriers in getting this lifesaving medication to women, so the development of a related, oral option may increase treatment access," Deligiannidis noted.

Both drugs are versions of allopregnanolone, a neuro-active steroid that is a byproduct of the hormone progesterone. Levels of allopregnanolone can rise dramatically during pregnancy and then crash after childbirth, potentially contributing to postpartum depression.

"Although it is not yet known exactly how zuranolone has rapid antidepressant effects, research suggests that neuro-steroids like zuranolone work to support brain health by rapidly reducing stress and restoring healthy brain network connections," Deligiannidis explained.

The most common side effects with zuranolone were sleepiness, dizziness, sedation and headache.

Because of the danger of sedation, the FDA has put a black box warning



on Zurzuvae's labeling, cautioning that users should not drive or operate <u>heavy machinery</u> within 12 hours of taking the pill.

"Since zuranolone is an acute, 14-day treatment course, the medication is not taken chronically, and side effects should be confined to the short-treatment course," Deligiannidis said. The drug should be taken in the evening along with "a fatty meal," the FDA noted in its approval.

Women's health experts are excited about the new option to treat postpartum depression.

"This could be a big deal," said Dr. Misty Richards, an assistant clinical professor of child and adolescent psychiatry and obstetrics and gynecology at the University of California, Los Angeles.

Timing is of the essence when treating postpartum depression, Richards added.

"Symptoms can compromise the bonding of parents to the baby and the attachment of babies to the parent," she explained.

Zurzuvae's approval "will, to a great degree, have a very positive impact on the treatment of postpartum depression," agreed Dr. Nirmaljit Dhami, a psychiatrist at El Camino Health in Mountain View, Calif.

"The hope is that this medication will lead to permanent remission of symptoms and that the patient will not need to take it on an ongoing basis," Dhami added.

Women experiencing symptoms of postpartum depression should not suffer in silence, she said.

"Let your support system know if you are having these feelings and



symptoms," Dhami said. "You are not alone and not at fault. This condition is treatable, so there is hope."

More information: Learn more about <u>postpartum depression</u> at the American College of Obstetricians and Gynecologists.

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