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Zurzuvae (*zuranolone*)

An overview of Zurzuvae and why it is authorised in the EU

What is Zurzuvae and what is it used for?

Zurzuvae is an antidepressant medicine used to treat postpartum depression in adults.

Postpartum depression is depression that affects individuals after childbirth, with symptoms such as persistent feelings of sadness, anxiety, and fatigue.

Zurzuvae contains the active substance zuranolone.

How is Zurzuvae used?

Zurzuvae is available as capsules to be taken by mouth once a day in the evening. The medicine is taken for 14 days and can be used alone or in addition to other antidepressant treatment that the patient may already be taking.

The medicine can only be obtained with a prescription.

For more information about using Zurzuvae, see the package leaflet or contact your doctor or pharmacist.

How does Zurzuvae work?

The active substance in Zurzuvae, zuranolone, increases the activity of the neurotransmitter GABA, which is involved in regulating mood. Neurotransmitters such as GABA are chemicals that allow nerve cells to communicate with each other. In the brain, GABA reduces the ability of nerve cells to communicate, which has a calming effect. By increasing GABA's effects, zuranolone helps to improve mood.

What benefits of Zurzuvae have been shown in studies?

A main study involving 200 women with severe postpartum depression found that Zurzuvae is more effective than placebo (a dummy treatment) at improving symptoms of depression, as measured using the Hamilton depression rating scale (also called HAMD-17). A reduction in HAMD-17 score indicates an improvement in symptoms.

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In the study, women took Zurzuvae or placebo for 14 days. By the 15th day, women treated with Zurzuvae had a reduction of around 16 points in the HAMD-17 score, while those taking placebo had a reduction of around 12 points.

Supportive data showed that by the third day of treatment, the score had dropped by around 10 points in women who were taking Zurzuvae, compared with around 6 points in those taking placebo. Furthermore, 45 days after starting treatment, the HAMD-17 score was around 18 points lower for women who had taken Zurzuvae and around 14 points lower for those on placebo.

What are the risks associated with Zurzuvae?

For the full list of side effects and restrictions with Zurzuvae, see the package leaflet.

The most common side effects with Zurzuvae (which may affect more than 1 in 10 people) include sleepiness, dizziness and drowsiness.

Zurzuvae must not be taken during pregnancy.

Why is Zurzuvae authorised in the EU?

At the time of authorisation, there was an unmet need for treatment of postpartum depression that quickly takes effect. Zurzuvae was shown to be effective at bringing about a rapid improvement in symptoms of the condition, and the improvement was maintained throughout the study. The side effects were generally mild and tended to become less frequent after several days of treatment. The European Medicines Agency therefore decided that Zurzuvae's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Zurzuvae?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Zurzuvae have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Zurzuvae are continuously monitored. Suspected side effects reported with Zurzuvae are carefully evaluated and any necessary action taken to protect patients.

Other information about Zurzuvae

Zurzuvae received a marketing authorisation valid throughout the EU on 17 September 2025.

Further information on Zurzuvae can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/zurzuvae.

This overview was last updated in 09-2025.