Brexanolone (brex AN oh lone)

- **Zulresso®**
  - Injection: 100 mg/20 mL

If you or someone you know is in crisis, please call/text 988 to speak with a trained crisis counselor 24/7 and/or call 911 for emergency services. A help line and other resources are also available through the National Alliance on Mental Illness at nami.org.

What is brexanolone and what does it treat?

Brexanolone is an antidepressant medication that works in the brain. It is approved for the treatment of postpartum depression (PPD) in individuals 15 years of age and older.

Symptoms of postpartum depression include:

- Feeling sad, hopeless, empty, or overwhelmed
- Crying more often than usual or for no apparent reason
- Worrying or feeling overly anxious
- Oversleeping, or being unable to sleep even when her baby is asleep
- Having trouble concentrating, remembering details, and making decisions
- Experiencing anger or rage
- Losing interest in activities that are usually enjoyable
- Suffering from physical aches and pains, including frequent headaches, stomach problems, and muscle pain
- Eating too little or too much
- Withdrawing from or avoiding friends and family
- Having trouble bonding or forming an emotional attachment with her baby
- Persistently doubting her ability to care for her baby
- Thinking about harming herself or her baby

What is the most important information I should know about brexanolone?

Brexanolone may cause you to feel very sleepy (excessive sedation) or pass out (loss of consciousness). Your health care provider should check you for symptoms of excessive sleepiness every 2 hours while you are awake. They should also continuously monitor the oxygen level of your blood using a test called pulse oximetry.

During your brexanolone infusion, tell your health care provider right away if you feel like you cannot stay awake during the time you are normally awake or if you feel like you are going to pass out. Your health care provider may lower your dose or stop the infusion until your symptoms go away.

You must have a caregiver or family member with you to help care for your child(ren) during your brexanolone infusion.

Because of the risk of serious harm resulting from excessive sedation or sudden loss of consciousness, brexanolone is only available through a restricted program called ZULRESSO REMS.

All FDA warnings are at the end of this fact sheet. Please consult them before taking this medication.

Are there specific concerns about brexanolone and pregnancy?

It is not known if brexanolone will harm your unborn baby. However, based on how the medication works in the body and data from animal studies, brexanolone exposure may cause harm to the fetus.

There is a pregnancy registry for females exposed to brexanolone during pregnancy. The purpose of the registry is to collect information about the health of females exposed to brexanolone and their baby. If you become pregnant during treatment with brexanolone, talk to your health care provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/.

Let your health care provider know if you are breastfeeding or plan to breastfeed. Brexanolone passes into breast milk. Talk to your health care provider about the risks and benefits of breastfeeding and about the best way to feed your baby while receiving brexanolone.

What should I discuss with my health care provider before taking brexanolone?

- Symptoms of your condition that bother you the most
- If you have thoughts of suicide or harming yourself
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- If you experience side effects from your medications, discuss them with your provider. Some side effects may pass with time, but others may require changes in the medication.
- Any other psychiatric or medical problems you have, including kidney problems.
- All other medications you are currently taking (including over the counter products, herbal and nutritional supplements) and any medication allergies you have.
- Other non-medication treatment you are receiving, such as talk therapy or substance abuse treatment. Your provider can explain how these different treatments work with the medication.
- If you are pregnant, plan to become pregnant, or are breastfeeding
- If you drink alcohol or use drugs

How should I take brexanolone?

Brexanolone is given to you by continuous intravenous (IV) infusion. Your brexanolone infusion will last for a total of 60 hours (2.5 days). A health care provider must be available on site to continuously monitor you for the duration of the infusion.

What should I avoid while taking brexanolone?

Brexanolone may make you feel dizzy and sleepy. Do not drive a car or do other activities that require mental alertness after your brexanolone infusion until your feeling of sleepiness has completely gone away.

Do not drink alcohol during your brexanolone infusion. Drinking alcohol while receiving brexanolone can increase the risk of excess sleepiness.

What are the possible side effects of brexanolone?

Common side effects

Sleepiness, dry mouth, dizziness, passing out, or flushing of the skin or face

Rare/serious side effects

Brexanolone can cause excessive sedation and loss of consciousness. Tell your health care provider right away if you feel like you cannot stay awake during the time you are normally awake or if you feel like you are going to pass out during your brexanolone infusion. Your health care provider may lower your dose or stop the infusion until your symptoms go away. Because of the risk of serious harm resulting from excessive sedation or sudden loss of consciousness, brexanolone is only available through a restricted program called the ZULRESSO REMS.

Suicidal Thoughts or Actions in Children and Adults

Postpartum depression and certain other psychiatric disorders are themselves associated with the risk of suicide. Women with postpartum depression may experience worsening of their depression and/or emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications. This risk may persist until significant remission occurs. Brexanolone and other antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger. All patients being treated with antidepressants for any indication should watch for and notify their health care provider for worsening symptoms, suicidality and unusual changes in behavior, during treatment.

Are there any risks for taking brexanolone for long periods of time?

There is a risk of physical and/or emotional dependence (addiction). Talk to your provider about the risk.

What other medications may interact with brexanolone?

Central nervous system depressants, such as benzodiazepines, sleep medications (e.g., suvorexant (Belsomra®, zolpidem (Ambien®)), or opioids, may enhance the feeling of sedation when taken with brexanolone. People taking other antidepressants might also experience more sedation while receiving brexanolone.

Summary of Black Box Warnings

In clinical studies, brexanolone caused excessive sedation that required a dose change in some patients during the infusion compared to the placebo treated patient. Some patients reported to have loss of consciousness or altered state of consciousness during the brexanolone infusion. After stopping the medication, the time to full recovery from loss of or altered state of consciousness ranged from 15 to 60 minutes. Patients should be cautioned against engaging in potentially hazardous activities requiring mental alertness, such as driving, after the infusion until any sedative effects have completely gone away. Patients must have someone with them during interactions with their child(ren) while receiving the infusion because of the potential for excessive sedation and sudden loss of consciousness. Patients, their families, and caregivers should be alert to the emergency of excessive sedation and sudden loss of consciousness. If these symptoms emerge, they should be reported to the patient's prescriber or health care professional.