Zulresso™
(brexanolone) injection IV
for intravenous use

What You Need to Know About ZULRESSO™

Patient Information Guide

Patients:
Your Healthcare Provider will go over this ZULRESSO REMS Patient Information Guide with you. It is important to ask any questions you may have. Keep this Guide for important information about ZULRESSO.

Healthcare Providers:
Counsel your patient with this Guide and give her a copy.

You and your Healthcare Provider have chosen ZULRESSO for your treatment. You can only get ZULRESSO at a ZULRESSO REMS certified Healthcare Setting, like a hospital or infusion center. Your Healthcare Provider has a list of sites where you can get ZULRESSO. Together, you can pick the one that works best for you.

What is ZULRESSO?

ZULRESSO is a medicine used to treat postpartum depression (PPD) in adults. Symptoms of PPD can start during or after pregnancy. Before receiving ZULRESSO, tell your Healthcare Provider if you are pregnant or think you may be pregnant. It is not known if ZULRESSO will harm your unborn baby.

How is ZULRESSO given?

ZULRESSO is given directly into your vein as an intravenous (IV) solution. This can also be called an infusion. The infusion lasts 60 hours without stopping. That's 2.5 days.

A trained Healthcare Provider will give you ZULRESSO at a ZULRESSO REMS certified Healthcare Setting. They will be able to help you with any side effects that might happen.

What are the serious risks of ZULRESSO?

- Risk of serious harm from extreme sleepiness (excessive sedation) or passing out (loss of consciousness) during the infusion

During the infusion, patients treated with ZULRESSO may get extremely sleepy. Sometimes they may not be easily awakened. This is different from normal sleep where you drift into sleep naturally and can wake up easily. Sudden loss of consciousness (passing out) can occur in some patients.

Because this could cause serious harm, you will be monitored during your treatment. Your Healthcare Provider will check you for symptoms of excessive sleepiness every 2 hours. Also, someone will need to care for your child(ren) and be in the room with you if you are with your child(ren) during the infusion.

What are the symptoms that I should be aware of?

It is important to tell your Healthcare Provider if you have any of the following symptoms while getting ZULRESSO:

- Feeling more sleepy than usual (you cannot stay awake when you are trying to stay awake)
- Having a hard time paying attention
- Having trouble following simple instructions
- Feeling lightheaded or dizzy or like you are going to pass out

These are not all the possible side effects of ZULRESSO. See the ZULRESSO Medication Guide for more information or talk to your Healthcare Provider further.

What should I do if I start to feel the symptoms listed above?

- If you're holding your baby, put your baby down.
- Sit or lie down.
- Tell your Healthcare Provider right away.

Your Healthcare Provider may stop your infusion with ZULRESSO. During clinical trials, once ZULRESSO was stopped, patients who passed out woke up after a short time. You and your Healthcare Provider will decide whether to continue ZULRESSO.

How should I prepare for my infusion?

- Work with your Healthcare Provider to choose a certified Healthcare Setting that works best for you.
- Find childcare for the 2.5 days of your treatment.
- Tell your Healthcare Provider about all the medicines you take.
- Especially tell your Healthcare Provider if you take:
  - Other antidepressants
  - Opioids
  - Other medicines that make you sleepy, such as benzodiazepines

What is a Risk Evaluation and Mitigation Strategy (REMS)?

REMS is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medicines with serious safety concerns. Drug companies and prescribers must take extra steps to make sure the benefits of using the drug are more than the risks. FDA must approve these steps as part of a REMS.

Why does ZULRESSO have a REMS?

ZULRESSO has a REMS because of the serious harm that could happen from extreme sleepiness or passing out during the infusion. You must be enrolled in the ZULRESSO REMS to get ZULRESSO.

What do I need to do to enroll in the ZULRESSO REMS?

- Complete the ZULRESSO REMS Patient Enrollment Form. Someone at the REMS certified Healthcare Setting will help you.
- Please look over and sign the Patient Enrollment Form.
- The information you provide will be stored in a database. The database is secure and private. The database is called the REMS Patient Registry. Information about all patients who get ZULRESSO in the United States will be stored in this database. Your personal information will only be used for the ZULRESSO REMS.

Additional questions

Talk with your Healthcare Provider if you would like more information.

If you have questions about the ZULRESSO REMS, visit **www.zulressorems.com** or call **844-472-4379.**

To report side effects, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 800-FDA-1088 or www.fda.gov/medwatch.

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