

Experiencing side effects with your antidepressant?

Talk to your doctor about a different treatment option for major depressive disorder (MDD).

Increased risk of suicidal thoughts and actions. EXXUA™ (gepirone) and other antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger, especially within the first few months of treatment or when the dose is changed. Depression or other mental illnesses are the most important causes of suicidal thoughts or actions.

What is EXXUA? EXXUA is a prescription medicine used to treat adults with a certain type of depression called major depressive disorder (MDD). **EXXUA is not for use in children.**

Important Safety Information

How can I watch for and try to prevent suicidal thoughts and actions in myself or family member?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings or if you develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, feelings, or if you develop suicidal thoughts or actions.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider or get emergency medical help right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

Please see additional Important Safety Information throughout, [Full Prescribing Information](#), and [Medication Guide](#).

Side effects can affect your sexual health¹



Major depressive disorder (MDD) can have a negative impact on your overall health, including your sexual health.^{1,2} Taking an antidepressant may help, but some antidepressants may also cause sexual side effects.³

To get a snapshot of how MDD or your antidepressant may be impacting your sexual health, complete the checklist below.

My depression symptoms (check all that apply):

- ☐ Persistent sadness
- ☐ Low energy
- ☐ Low self-esteem
- ☐ Feelings of failure
- ☐ Difficulty/slowness with everyday activities

Side effects I am experiencing (check all that apply):

- ☐ Reduced sexual desire or satisfaction
- ☐ Difficulty with orgasm
- ☐ Difficulty maintaining an erection
- ☐ Weight gain

Bring this list to your next doctor visit. If any of the items you checked are making you feel less connected in your relationships, you can ask your doctor about other potential treatment approaches.

Explore how sexual side effects can affect your progress on the next page.

Important Safety Information (cont)

Do not take EXXUA if you:

- are allergic to EXXUA or any of the ingredients in EXXUA. See enclosed Medication Guide for a complete list of ingredients in EXXUA.
- have a prolonged QTc interval greater than 450 msec or congenital long QT syndrome.
- are taking medicines known as strong CYP3A4 inhibitors. Ask your healthcare provider if you are not sure if you are taking one of these medicines.
- have severe liver problems.
- are taking, or have stopped taking within the last 14 days, a medicine called a monoamine oxidase inhibitor (MAOI), including the antibiotic linezolid or intravenous methylene blue. Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid or intravenous methylene blue.
 - Do not start taking an MAOI for at least 14 days after you have stopped treatment with EXXUA.

Before taking EXXUA, tell your healthcare provider about all your medical conditions, including if you:

- have, or have a family history of, bipolar disorder, mania, or hypomania
- have any heart problems, including heart failure, recent heart attack, high blood pressure, a slow heart rate or heart rhythm problems
- have a history of electrolyte problems, including low potassium or low magnesium
- have liver problems
- have kidney problems
- are pregnant or plan to become pregnant. EXXUA may harm your unborn baby. Taking EXXUA during the third trimester of pregnancy may cause the baby to have withdrawal symptoms, or breathing, temperature control, feeding, or other problems after birth. Talk to your healthcare provider about the risks to the baby if you take EXXUA during pregnancy.

Please see additional Important Safety Information throughout, [Full Prescribing Information](#), and [Medication Guide](#).

Sexual side effects are a challenge for many people with MDD³



Up to 70% of people taking an antidepressant have sexual side effects³



SSRIs and SNRIs, the most common antidepressants, are known to cause sexual side effects. This may be due to their actions on a wide range of different serotonin receptors in the brain.^{3,4}

Sexual side effects can worsen depression symptoms¹

They can also worsen self-esteem and potentially reverse the improvements you experienced when you started taking your treatment.^{5,6}

Sexual side effects are a leading cause of people stopping their antidepressant treatment^{5,6}

It's hard to feel better when you feel disconnected from your most important relationships.

SSRI=selective serotonin reuptake inhibitor; SNRI=serotonin norepinephrine reuptake inhibitor.

You don't have to stop treatment altogether. There are different options.

Your doctor can help you address sexual side effects. They understand the importance of intimacy and can determine which treatment approach may be right for you.

Important Safety Information (cont)

Before taking EXXUA, tell your healthcare provider about all your medical conditions, including if you: (cont)

- Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with EXXUA.
- There is a pregnancy registry for females who are exposed to EXXUA during pregnancy. The purpose of the registry is to collect information about the health of females exposed to EXXUA and their baby. If you become pregnant during treatment with EXXUA, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/>.
- are breastfeeding or plan to breastfeed. It is not known if EXXUA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with EXXUA.
 - If you breastfeed during treatment with EXXUA, call your healthcare provider if the baby develops sleepiness or fussiness, or is not feeding or gaining weight well.

Tell your healthcare provider about all the medicines you take, including prescription and medicines, vitamins, and herbal supplements. EXXUA and other medicines may affect each other causing possible serious side effects. EXXUA may affect the way other medicines work and other medicines may affect the way EXXUA works.

Especially tell your healthcare provider if you take diuretics, corticosteroids, medicines used to treat migraine headaches called triptans, or medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), or tricyclic antidepressants.

Your healthcare provider can tell you if it is safe to take EXXUA with your other medicines. Do not start or stop any other medicines during treatment with EXXUA without talking to your healthcare provider first. Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

What are the possible side effects of EXXUA? EXXUA may cause serious side effects, including:

- **Changes in the electrical activity of your heart called QT prolongation.** QT prolongation can cause irregular heartbeats that can be life-threatening or lead to death. Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and will also do blood tests to check your levels of body salts (electrolytes) before and during treatment with EXXUA. Your healthcare provider may check your electrolytes more often during treatment if you have heart failure, a slow heart rate, abnormal levels of electrolytes in your blood, or if you take a medicine that can prolong the QT interval of your heartbeat. Tell your healthcare provider right away if you have an irregular heartbeat or feel dizzy, lightheaded, or faint during treatment with EXXUA.

Please see additional Important Safety Information throughout, [Full Prescribing Information](#), and [Medication Guide](#).

EXXUA is a first-of-its-kind treatment



It works in a different way so you can enjoy life your way

Common side effects in studies of EXXUA included dizziness, nausea, insomnia, abdominal pain, and indigestion.

-  Shown to improve symptoms in as few as 3 to 4 weeks^{7,8*}
-  No product warnings were required about sexual side effects⁹
-  No clinically significant increase in body weight^{7,8†}
-  One tablet once a day
 - EXXUA is taken on its own, not as an "add-on" treatment

*In two clinical studies, EXXUA improved symptoms of depression compared with placebo using the Hamilton Depression Rating Scale (HAMD-17), a questionnaire that assesses the severity of depression.⁹

†In clinical studies, people taking EXXUA gained an average of 0.7 to 2.2 pounds.^{7,8}

Ask your doctor about EXXUA at your next visit.

Here are some ways to start talking to your doctor about certain side effects:

"Some of my depression symptoms are getting better, but the sexual side effects are affecting my relationship. Is there a treatment that can give me one without the other?"

"I'm interested in EXXUA because I've heard it can help avoid certain side effects that my current antidepressant is causing. Is EXXUA an appropriate option for me?"

"I think my antidepressant is dulling my feelings of intimacy (eg, my libido, my ability to orgasm) with my partner. Would EXXUA be an appropriate option to try instead?"

"I've gained some weight since I started my antidepressant and I haven't changed my diet or exercise. Could it be the drug?"

"I've heard EXXUA works differently and doesn't cause sexual dysfunction or significant weight gain. Would that be right for me?"

Important Safety Information (cont)

What are the possible side effects of EXXUA? EXXUA may cause serious side effects, including: (cont)

• **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when EXXUA is taken with certain other medicines. **Call your healthcare provider or go to the nearest hospital emergency room right away** if you have any of the following signs and symptoms of serotonin syndrome:

- Agitation
- Confusion
- Coma
- Sweating
- Flushing
- Seizures
- Nausea, vomiting, and diarrhea
- See or hearing things that are not real (hallucinations)
- Fast Heartbeat
- Blood Pressure Changes
- Shaking (tremors), stiff muscles, or muscle twitching
- Dizziness
- High body temperature (hyperthermia)
- Loss of coordination

• **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take EXXUA. Symptoms may include:

- Greatly increased energy
- Racing thoughts
- Unusually grand ideas
- Talking more or faster than usual
- Severe problems sleeping
- Reckless behavior
- Excessive happiness or irritability

• **The most common side effects of EXXUA include:** dizziness, nausea, headache, trouble sleeping, stomach (abdominal) pain, and upset stomach.

These are not all the possible side effects of EXXUA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General Information about the safe and effective use of EXXUA

Medicines are sometimes prescribed for purposes other than listed in this brochure. Do not use EXXUA for a condition for which it was not prescribed. Do not give EXXUA to other people, even if they have the same symptoms you have. It may harm them. You can ask your doctor or pharmacist for information about EXXUA that is written for healthcare professionals.

Please see additional Important Safety Information throughout, [Full Prescribing Information](#), and [Medication Guide](#).

References: 1. Chokka P, Hankey JR. Assessment and management of sexual dysfunction in the context of depression. *Ther Adv Psychopharmacol*. 2017;8(1):13–23. 2. Blasco BV, García-Jiménez J, Bodoano I, Gutiérrez-Rojas L. Obesity and depression: its prevalence and influence as a prognostic factor: a systematic review. *Psychiatry Investig*. 2020;17(8):715–724. 3. Carvalho AF, Sharma MS, Brunoni AR, Vieta E, Fava GA. The safety, tolerability and risks associated with the use of newer generation antidepressant drugs: a critical review of the literature. *Psychother Psychosom*. 2016;85(5):270–288. 4. Fabre LF, Clayton AH, Smith LC, Goldstein I, Derogatis LR. The effect of gepirone-ER in the treatment of sexual dysfunction in depressed men. *J Sex Med*. 2012;9(3):821–829. doi: 10.1111/j.1743-6109.2011.02624.x 5. Jacobsen PL, Thorley EM, Curran C. Real-world patient experience with sexual dysfunction and antidepressant use in patients with self-reported depression: a cross-sectional survey study. *Neurol, Psychiatry, and Brain Res*. 2020;36:57–64. 6. Lorenz TK, Johnson MF, Clayton AH. Effects of gepirone-ER on sexual function in patients with major depressive disorder. *J Clin Psychiatry*. 2024;85(4):24m15357. doi: 10.4088/JCP.24m15357 7. Data on file. Clinical Trial Report 134001. Organon Inc. 2001. 8. Data on file. Clinical Study Report FKGBE007. Fabre-Kramer Pharmaceuticals, Inc. 2005. 9. EXXUA™ (gepirone). Prescribing Information. Fabre-Kramer Pharmaceuticals, Inc.



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