

MEDICATION GUIDE
EXXUA™ (EKS-shoo-uh)
(gepirone)
extended-release tablets

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

EXXUA may cause serious side effects, including:

- **Increased risk of suicidal thoughts and actions.** EXXUA 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. EXXUA is not for use in children.

- Depression or other mental illnesses are the most important causes of suicidal thoughts or actions.

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

What is EXXUA?

EXXUA is a prescription medicine used to treat adults with a certain type of depression called major depressive disorder (MDD).

It is not known if EXXUA is safe and effective in children.

Do not take EXXUA if you:

- are allergic to EXXUA or any of the ingredients in EXXUA. See the end of this 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.
 - 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 headache 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.

How should I take EXXUA?

- Take EXXUA exactly as your healthcare provider tells you to take it. Do not change the dose or stop taking EXXUA without first talking to your healthcare provider.
- Take EXXUA 1 time each day with food at about the same time each day.
- Swallow EXXUA tablets whole. Do not break, chew, crush, or dissolve tablets.
- If you miss a dose, take it as soon as you remember. If it is time for your next dose, skip the missed dose and take only your regularly scheduled dose. Do not take 2 doses at the same time to make up for a missed dose.
- If you take too much EXXUA, call your healthcare provider or Poison Help Line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are the possible side effects of EXXUA?

EXXUA may cause serious side effects, including:

- See “**What is the most important information I should know about EXXUA?**”
- **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.
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when EXXUA is taken with certain other medicines. See “**Do not take EXXUA if you:**”. **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
 - fast heartbeat
 - sweating
 - flushing
 - seizures
 - nausea, vomiting, and diarrhea
 - seeing or hearing things that are not real (hallucinations)
 - coma
 - 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.

How should I store EXXUA?

- Store EXXUA at room temperature between 68°F to 77°F (20°C to 25°C)
- Protect from high humidity and moisture.
- **Keep EXXUA and all medicines out of the reach of children.**

General information about the safe and effective use of EXXUA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. 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 health professionals.

What are the ingredients in EXXUA?

Active ingredient: gepirone

Inactive ingredients: colloidal silicon dioxide, Hypromellose, iron oxide (red and/or yellow as coloring agents), magnesium stearate, and microcrystalline cellulose.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued 09/2023

Product of Italy

Manufactured by:

Mission Pharmacal Company
San Antonio, TX USA 78230

Distributed by:

Aytu Therapeutics, LLC
Denver, CO USA 80237

I1121MGR0825

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