

Get to know EXXUA

A treatment for adults with
major depressive disorder (MDD)



exxua[™]
(gepirone)
extended-release tablets
18.2 mg, 36.3 mg, 54.5 mg, 72.6 mg

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

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.**

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

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

Is your current antidepressant not living up to expectations?

Many antidepressants, like selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs), are associated with unwanted side effects—like a decrease in sexual function and/or weight gain.

If you are still experiencing depression with SSRIs or SNRIs or if your side effects are intolerable, you should talk to your doctor.

It might be time for a different approach. Ask if EXXUA may be right for you.

Important Safety Information (cont)

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.

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SSRIs, SNRIs, and EXXUA: What's the difference?

How SSRIs or SNRIs work

How antidepressants work is pretty complex. Scientists think it involves chemical messengers in the brain.

SSRIs and SNRIs are thought to work by **broadly interacting** with receptors that increase serotonin and norepinephrine, chemical messengers in the brain. This may help improve depression symptoms, but **may considerably impact sexual function and cause weight gain**.

EXXUA is not an SSRI or SNRI

EXXUA is thought to work by **selectively targeting** a specific serotonin receptor associated with depression symptoms—while **potentially avoiding side effects like sexual dysfunction and weight gain**.

EXXUA works in a different way to help treat your depression symptoms.

Important Safety Information (cont)

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

- 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.

For MDD, EXXUA is a first-of-its-kind treatment

In two clinical studies, EXXUA improved symptoms of depression in the Hamilton Depression Rating Scale (HAMD-17) versus placebo. The HAMD-17 is a questionnaire used to assess the severity of depression.¹

Most people in the clinical studies saw improvements in their symptoms as soon as they reached the optimal dose (54.5 mg or 72.6 mg).

Is EXXUA right for me?

People with certain heart issues should not take EXXUA. Your doctor may perform an electrocardiogram (ECG) before and during your initial experience with EXXUA to ensure there are no issues with you taking the medication.

Important Safety Information (cont)

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

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An option that may better fit your life

In clinical studies, EXXUA helped improve depression symptoms. Common side effects experienced include dizziness, nausea, insomnia, abdominal pain, and indigestion—but most did not report sexual dysfunction or weight gain.



Improves depression symptoms¹



No product warnings were required about sexual dysfunction¹



No clinically significant increase in body weight compared to placebo^{2,3}

Important Safety Information (cont)

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: (cont)

- 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

Once-daily EXXUA is an extended- release tablet

Extended-release means the medication goes into your system slowly, throughout the day. So you only need one tablet, once daily. **Simply take EXXUA by mouth at the same time each day.**

**93% of people stayed on EXXUA
during clinical studies.¹**

In clinical studies, only 2–3% of people stopped taking EXXUA due to dizziness and/or nausea.^{2,3*}

Side effects you may experience^{1,3}

Common side effects include dizziness, nausea, insomnia, abdominal pain, and indigestion. Dizziness is typically mild. During a clinical study, people affected by dizziness dropped from Week 1 (34%) to Week 2 (19%). Some people find taking EXXUA with food or in the evening may lessen nausea.

Talk to your doctor if you need help managing side effects.

*In two phase 3 studies of over 400 people.

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

2 weeks to adjust to medication

Your doctor will prescribe a 14-day starter pack. During this 2-week period, EXXUA is gradually increased to help your body adjust to medication.

14-DAY STARTER PACK			MONTHLY Rx
STEP 1	STEP 2	STEP 3	OPTIMAL*
DAYS 1-3 1 tablet once per day  18.2 mg Based on clinical response and tolerability →	DAYS 4-7 2 tablets once per day  18.2 mg  18.2 mg Based on clinical response and tolerability →	DAYS 8-14 3 tablets once per day  18.2 mg  18.2 mg  18.2 mg Based on clinical response and tolerability →	DAYS 15 & BEYOND 1 tablet once per day  54.5 mg If not optimized, doctor may increase to 72.6 mg  72.6 mg *In pivotal studies.

Important Safety Information (cont)

Do not take EXXUA if you: (cont)

- 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.

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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:

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- panic attacks
- trouble sleeping (insomnia)
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- 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

Important Safety Information (cont)

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

- 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 headaches called triptans, or medicines used

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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.
- **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

Important Safety Information (cont)

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EXXUA may cause serious side effects, including:
(cont)

- 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.

References: **1.** EXXUA™ (gepirone). Prescribing Information. Fabre-Kramer Pharmaceuticals, Inc. **2.** Data on file. Clinical Trial Report 134001. Organon Inc. 2001. **3.** Data on file. Clinical Study Report FKGBE007. Fabre-Kramer Pharmaceuticals, Inc. 2005.

I am excited about EXXUA

Some questions I have for my doctor are:

Is EXXUA right for me?

Could a different antidepressant help
resolve my depression symptoms?

Can EXXUA help with the side effects I've
been having on my current medication?

How long will it take for EXXUA to work?

What do I need to know about
switching to EXXUA?

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extended-release tablets
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Getting started with EXXUA?

START SAVING HERE



**Aytu
RxConnect®**

Predictable • Hassle Free • Affordable

Putting patients first.

Through RxConnect, you may reduce
your cost of EXXUA. Patients with
commercial insurance may **pay as
little as \$0** when a participating
pharmacy is used.

Check out the
website for
more details.



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BIOPHARMA

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