



**exxua**<sup>™</sup>

(gepirone)

extended-release tablets

18.2 mg, 36.3 mg, 54.5 mg, 72.6 mg

# Getting started with EXXUA

A guide to the first 2 weeks of  
treatment for adults with major  
depressive disorder (MDD)

**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.**

**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.

**Please see additional Important Safety Information throughout.**

**Please see [Full Prescribing Information](#).**

# Welcome to EXXUA!

## You're a step closer to starting your treatment journey

### Starting a new medication means making some changes.

Your doctor has given you this guide to make the transition a smooth one. It will help you understand and keep track of your first 2 weeks of taking EXXUA.

EXXUA is a medication for MDD that you take by mouth once per day, with food, at the same time each day.

When you start taking EXXUA, your doctor will prescribe a **starter pack, which is a 14-day supply of tablets**. During these first 2 weeks, the dose (the number of tablets you take daily) is increased gradually to let your body adjust to the medication.

### Important Safety Information (cont)

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

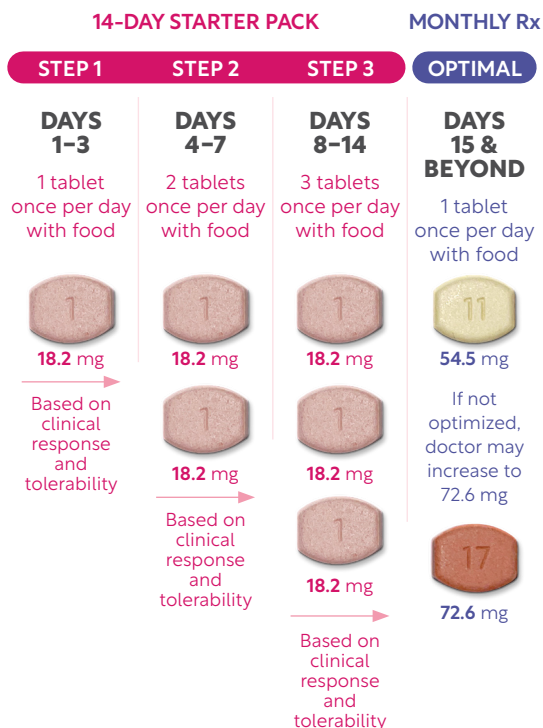
- Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, feelings, or if you develop suicidal thoughts or actions.

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The chart below shows how your dose will typically increase over the first 2 weeks, based on clinical response and tolerability.

Once you and your doctor determine your optimal dose, you will take **1 tablet once per day with food**. Most people in clinical studies saw improvements in their symptoms as soon as they reached an **optimal dose of 54.5 mg or 72.6 mg per day**.



### 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.

## Being aware of side effects

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Side effects can happen with EXXUA, especially **in the first few weeks as your body is adjusting to the medication**. It's important to let your doctor know about any side effects you might experience at your following appointment. They can help you manage them. In some cases, this might mean adjusting your dose of EXXUA.

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

**Dizziness is typically mild.** During a clinical study, the percentage of people affected by dizziness dropped from Week 1 (34%) to Week 2 (19%) and continued to go down from there.<sup>1</sup>

Some people find taking EXXUA with food or in the evening may lessen nausea.

When thinking about side effects, it helps to know that **93% of people in studies did not stop treatment due to side effects**.

### 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 monitor your heart.

## Keeping track of your treatment

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Ask your doctor for a 14-Day Dosing Tracker to help keep track of your daily dose of EXXUA during your first 2 weeks.



### 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
- 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.**  
**Please see [Full Prescribing Information](#).**

**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.

### 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

### 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

**Please see additional Important Safety Information throughout.**  
**Please see Full Prescribing Information.**

## 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 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

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**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: (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.

**Please see additional Important Safety Information throughout.  
Please see [Full Prescribing Information](#).**

**Reference: 1.** Data on file. Clinical Study Report FKGBE007. Fabre-Kramer Pharmaceuticals, Inc. 2005.



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