

Watch for Gepirone ER, a New Rx Antidepressant

Gepirone ER (*Exxua*) will be a new Rx med for depression in adults.

Gepirone works similarly to the anxiety med buspirone.

Reps will tout that gepirone doesn't have a warning about sexual dysfunction...which is common with other antidepressants (paroxetine, etc). But there's no good evidence that sexual side effects are less.

Plus gepirone has a checkered history.

FDA rejected it 3 times over 20 years...due to a stack of studies that don't find any benefit. Its approval now is based on 2 studies showing efficacy at 8 weeks...but there aren't good long-term data.

On top of that, about a third or more of patients taking gepirone ER report dizziness, nausea, or headache.

Expect that most adults with depression will still get a first-line treatment...such as an SSRI (sertraline, etc) or SNRI (duloxetine, etc).

If you get an Rx for *Exxua*, anticipate payer rejects. It'll likely cost at least \$500/month...versus about \$15 for generic SSRIs or SNRIs.

Watch out for look-alike/sound-alike meds. *Exxua* could be mistaken for *Euflexxa* or *Andexxa*...or gepirone for buspirone.

Double-check strengths of *Exxua* during order entry. The ER tabs come in 4 strengths, 18.2 mg...36.3 mg...54.5 mg...and 72.6 mg.

Expect most patients to start with one 18.2 mg tablet by mouth once daily...and increase based on response and tolerability.

For example, the dose may go up to 36.3 mg once daily on day 4...to 54.5 mg after day 7...and to 72.6 mg once daily after an additional week.

Notify your pharmacist about interactions. For instance, levels of gepirone ER may be increased by diltiazem, verapamil, or other meds.

Use labeling to promote proper administration. Patients should take gepirone ER "With food" and "Swallow whole"...for proper absorption.

Dispense a MedGuide to help warn about side effects and other risks (irregular heartbeats, thoughts of suicide, etc).

Review our resource, *Choosing and Switching Antidepressants*, for more about treatments for depression, side effects, etc.

Key References:

- FDA. Drug Approval Package: *Exxua*. November 28, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/021164Orig1s000TOC.cfm (Accessed April 18, 2024).
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