Zuranolone: The First Oral Neurosteroid for Postpartum Depression: Three Years Later

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Disclosures

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On medical advisory board with stock options for Cercle.ai

Objectives

1. Understand the neurosteroid pathology implicated in postpartum depression.
2. Appreciate the utility and potential of neurosteroid antidepressants in reproductive mood disorders.
3. Review three years of real-world effectiveness and post-marketing safety data since FDA approval.

The Need

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Peripartum Depression

20%
Most Common Complication of Childbirth

22.7%
of pregnancy related death due to mental illness

If left untreated:
- Mother-baby bonding
- Maternal suicide risk
- Language/problem solving development
- Behavioral issue
- Stress tolerance in children

Menstrual Related/Perimenopause Mood Disorders

65+%
Premenstrual worsening of MDD

45-68%
Perimenopausal Mood Symptoms

3-8%
Of reproductive age women have PMDD

The Ah-ha! for Allopregnanolone (ALLO)

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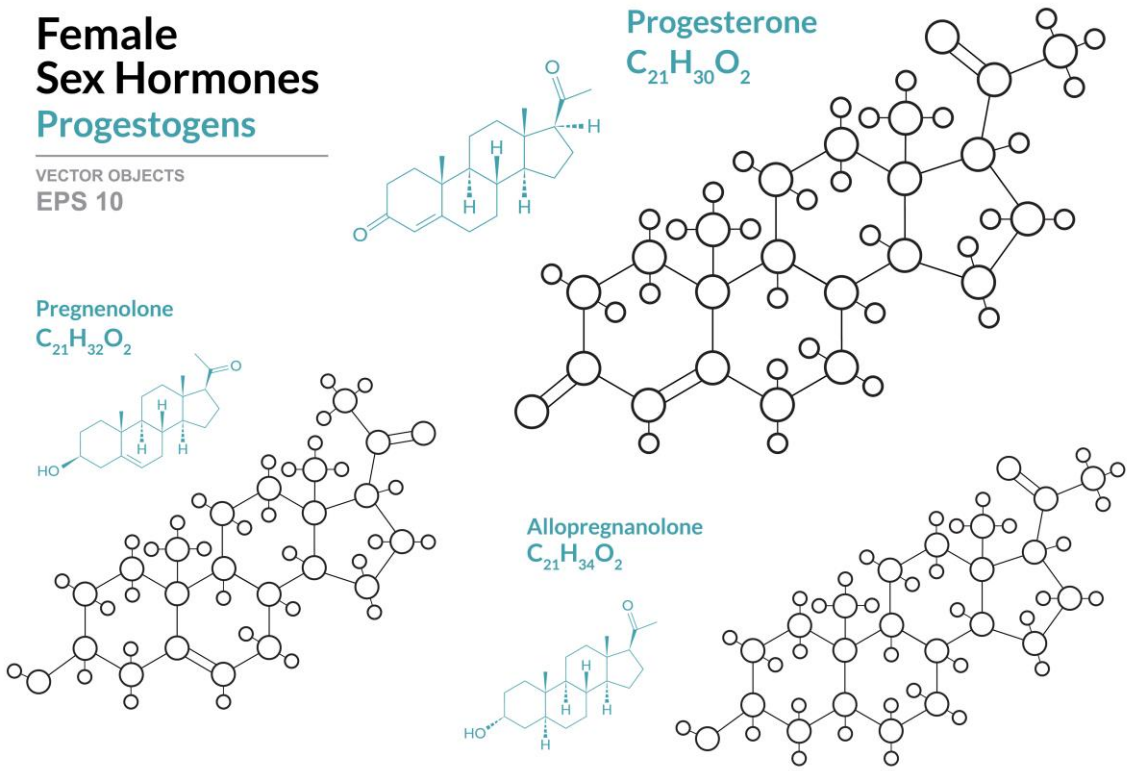
- Bench to bedside success for NIH/NIMH
- ALLO: Positive allosteric modulator of synaptic and extrasynaptic GABA-A receptors
- 1980s: ALLO as anxiolytic
- 2009: Maguire & Mody GABA-A receptor plasticity in pregnancy
- PPD and dysfunctional GABA-A
  - Differential sensitive to changes in ALLO in the postpartum
  - Lower levels of ALLO in postpartum



Brexanolone Studies

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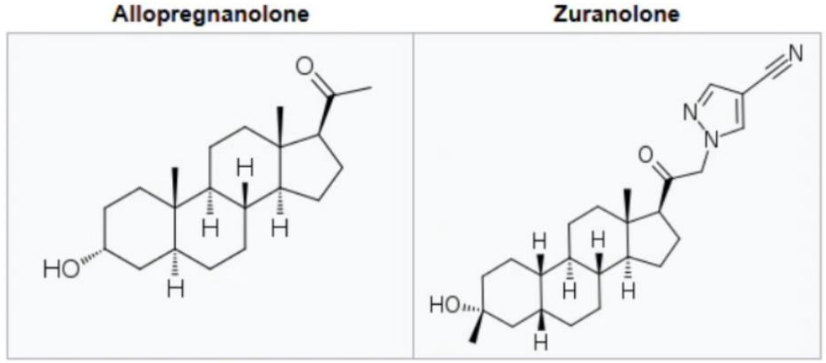
- Approved in 2019 for postpartum depression
- Synthetic version of ALLO: requiring IV infusion
- All phases: MDD from 3rd trimester (no earlier) to 12 weeks postpartum
- Phase 3: Two RCTS comparing baseline to post-infusion
  - Study 1: n = 138 with doses at 90 µg/kg vs. 60 µg/kg vs. placebo x 60 hours
    - Least-square (LS) mean reduction of 17.7 (p = 0.0252) vs. 19.6 (p = 0.0013) vs. 12 points on HAM-D
  - Study 2: n = 108 with 90 µg/kg vs. placebo x 60 hours
    - LS mean reduction 14.6 (p = 0.0160) vs. 12.1 points on HAM-D
  - Most common AE:
    - Headache (22 in brex vs. 13 placebo)
    - Dizziness (16 in brex vs. 5 placebo)
    - Somnolence (13 in brex vs. 5 placebo)

Zuranolone Studies

- Approved August 2023 for PPD, not for MDD
- Positive allosteric modulator of GABA-A receptors, orally formulated
- Phase 3 trials: Two RTCs, HAM-D change from baseline to day 15
  - Study 1: n = 153, dose = 30 mg x 14 days
    - HAM-D Improvement: 17.8 (Z) vs. 13.6 (P), p = 0.003
  - Study 2: n = 196, dose = 50 mg x 14 days
    - HAMD-D LSM change: 15.6 (Z) vs. 11.6 (P), p = 0001



2021 JAMA Psychiatry Study 1; 2023 AJP Study 2

Why Only PPD? Zuranolone's MDD Trials

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Zuranolone was also tested in general MDD — and fell short

- MOUNTAIN (30 mg, MDD): missed its Day 15 primary endpoint (LSM CFB -12.5 vs. -11.1 placebo, p = 0.116)
- WATERFALL (50 mg, MDD): met its endpoint (p = 0.0141), but the effect size was modest
- Despite WATERFALL and SHORELINE meeting their endpoints, the FDA issued a Complete Response Letter for the MDD indication in 2023 — effect sizes were judged too small for approval

Why PPD trials succeeded where MDD trials didn't

- PPD's sharp, hormonally-driven onset may better match zuranolone's rapid GABAergic mechanism than the more heterogeneous biology of general MDD

Clayton AH et al. J Clin Psychiatry. 2023;84:22m14445 (MOUNTAIN); Biogen/Sage press release, WATERFALL, 2021; Clinical TrialsArena, Aug 2023 (FDA CRL).

Zuranolone: 45-day outcomes

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eTable 7. HAMD-17 Response

Responders n (%)	Zuranolone (n=76)	Placebo (n=74)	OR	95% CI for OR	p-value
Day 3	30/74 (41)	20/74 (27)	1.79	(0.89, 3.60)	0.100
Day 8	49/75 (65)	33/74 (45)	2.31	(1.20, 4.45)	0.013
Day 15	53/74 (72)	35/73 (48)	2.63	(1.34, 5.16)	0.005
Day 21	53/74 (72)	41/73 (56)	1.85	(0.94, 3.64)	0.076
Day 45	55/73 (75)	39/69 (57)	2.28	(1.13, 4.60)	0.022

eTable 8. HAMD-17 Remission

Remitters n (%, total)	Zuranolone (n=76)	Placebo (n=74)	OR	95% CI for OR	p-value
Day 3	14/74 (19)	4/74 (5)	3.89	(1.24, 12.23)	0.020
Day 8	24/75 (32)	14/74 (19)	1.91	(0.89, 4.13)	0.099
Day 15	33/74 (45)	17/73 (23)	2.53	(1.24, 5.17)	0.011
Day 21	31/74 (42)	21/73 (29)	1.58	(0.79, 3.19)	0.198
Day 45	39/73 (53)	21/69 (30)	2.52	(1.26, 5.03)	0.009

Zuranolone: Anxiety/Insomnia

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Figure 2. Rapid and Sustained Improvement in Symptoms of Anxiety

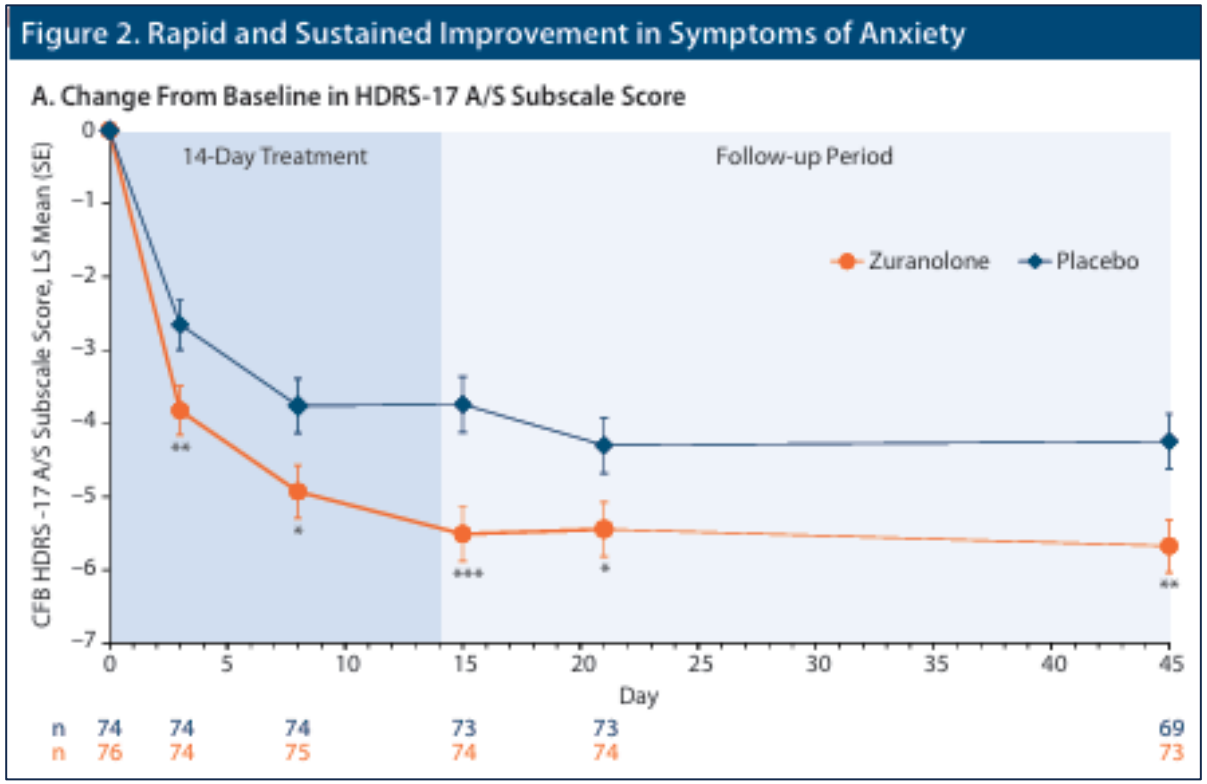
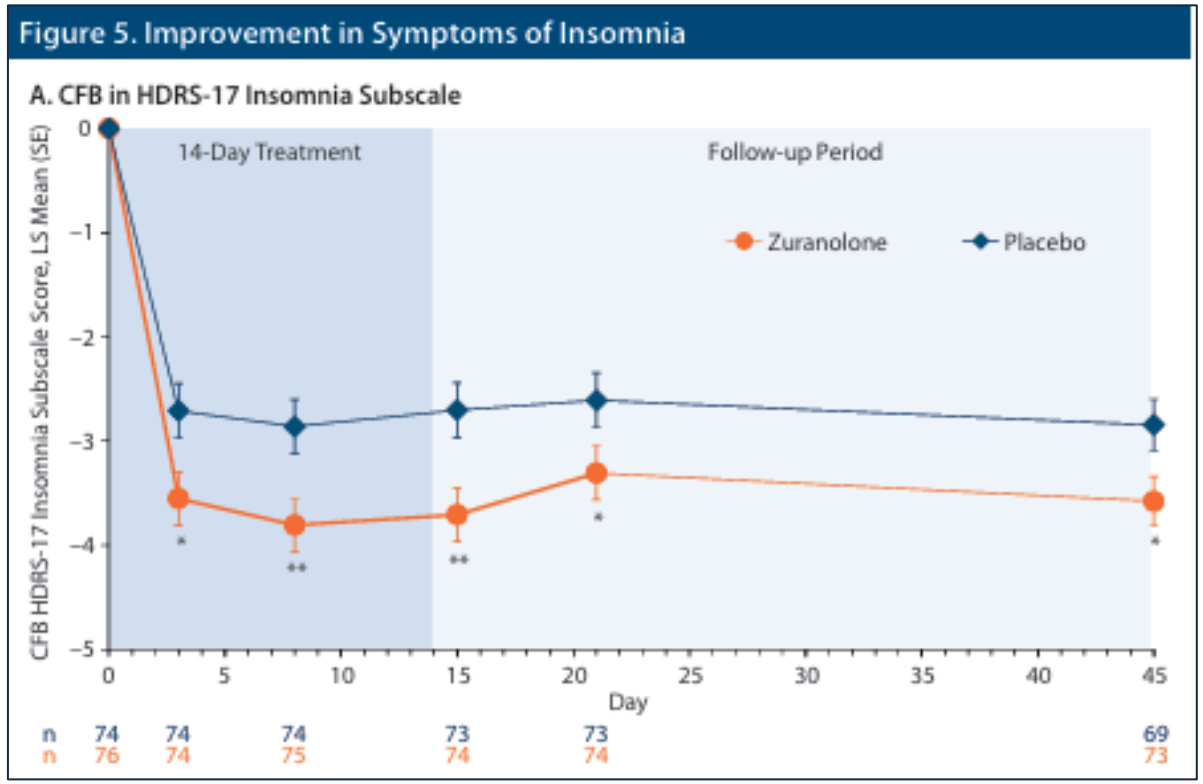


Figure 5. Improvement in Symptoms of Insomnia



Deligiannidis KM, Citrome L, Huang MY, Acaster S, Fridman M, Bonthapally V, Lasser R, Kanes SJ. Effect of zuranolone on concurrent anxiety and insomnia symptoms in women with postpartum depression. The Journal of Clinical Psychiatry. 2023 Jan 30;84(1):45307.

Zuranolone: Side Effects

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Coming Side Effects

- Somnolence (15%)
- Headache (9%)
- Drug-drug interactions CYP3A4

Table 2. Treatment-Emergent Adverse Events (TEAEs)[a]

Patients reporting TEAE	No. (%) Zuranolone, 30 mg (n = 78)	Placebo (n = 73)
Any AE	47 (60)	38 (52)
Severe AE	3 (4)	3 (4)
Serious AE	1 (1)	1 (1)
AE drug discontinuation	1 (1)	0
Death	0	0
Most common TEAEs, ≥5% patients occurring in either study arm		
Somnolence	12 (15)	8 (11)
Headache	7 (9)	9 (12)
Dizziness	6 (8)	4 (6)
Upper respiratory tract infection	6 (8)	1 (1)
Diarrhea	5 (6)	2 (3)
Sedation	4 (5)	0
Nausea	3 (4)	6 (8)
Vomiting	1 (1)	4 (6)
Abnormal dreams	0	4 (6)
Hyperhidrosis	0	4 (6)

Zuranolone: Breastfeeding

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ORIGINAL CONTRIBUTIONS

Zuranolone Concentrations in the Breast Milk of Healthy, Lactating Individuals

Results From a Phase 1 Open-Label Study

Deligiannidis, Kristina M. MD[1,2,3]; Bullock, Amy PhD[4]; Nandy, Indrani PhD[4]; Dunbar, Joi PharmD[4]; Lasser, Robert MD[4]; Witte, Michael PhD[4]; Leclair, Bridgette PharmD[5]; Wald, Jeffrey PhD[4]

Author Information

Journal of Clinical Psychopharmacology 44(

TABLE 4 - Summary of Estimated RIDs for Zuranolone 50 mg Across Different Infant Ages, Weights, and Daily Milk Intake Quantities

	Milk Intake					
	150 mL/kg per day			200 mL/kg per day		
	Infant Age					
	0–4 wk	4–12 wk	12–30 wk	0–4 wk	4–12 wk	12–30 wk
RID, %						
Mean (SD)	0.737 (0.363)	0.738 (0.363)	0.738 (0.363)	0.984 (0.484)	0.984 (0.484)	0.983 (0.484)
PI90*	0.31–1.44	0.31–1.45	0.31–1.44	0.42–1.92	0.42–1.91	0.41–1.92

Data are simulated in conjunction with an established population PK (PopPK) model that derived the mean zuranolone concentration in breast milk in a simulated population of adult women (n = 1000) receiving zuranolone 50 mg once daily for 14 days. Representative infant populations were modeled according to the World Health Organization child growth standards.

*Data are presented as 5th to 95th percentile range.

PI90, 90% prediction interval; PopPK, population pharmacokinetic; RID, relative infant dose; wk, week.

Three Years Later: Real-World Effectiveness

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- Mixed experiences
- A narrative of “not as good at brexanolone”
- Continued difficulty with prescribing/access
- PMDD patients
- Inability to do IIRs

First Pill for Postpartum Depression Shows Varied Real-World Results

Some women’s symptoms improved quickly after taking the pill, but depression persisted in others. Doctors are trying to learn which patients benefit, and why some don’t.

Samantha Cohn was hospitalized for weeks after trying to take her own life. To treat her mental health challenges the first pill specifically for postpartum depression. Madeline Gray for The New York Times

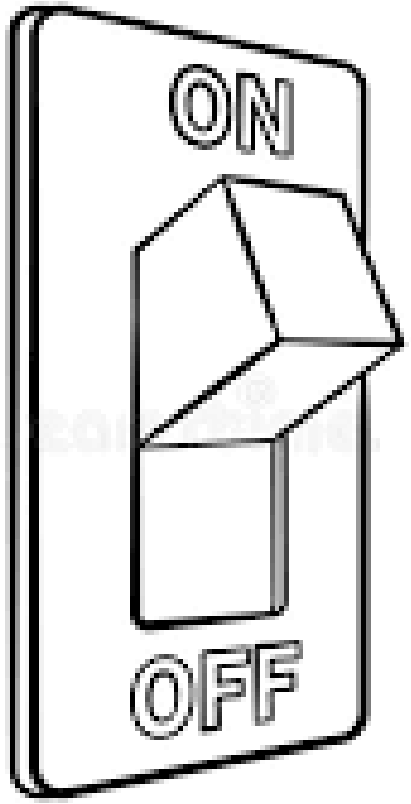
Listen · 13:20 min

By Pam Belluck

Pam Belluck, who covers maternal men across the country who experienced pos

July 22, 2025

Our Experience: it still worth it for the right patient



Three Years Later: Real-World Effectiveness

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Phase 4 Prospective Observational Study (AMCP/PSI, 2026), Baker, Nagle-Yang, Bian

- 191 participants tracked over 45 days across baseline severities (EPDS)
- Clinically meaningful symptom reduction by end of 14-day course; many reached full remission, sustained through Day 45
- ~Half of participants used zuranolone as standalone therapy, without additional psychiatric prescriptions
- Many patients safely continued breastfeeding during treatment

Baker LJ et al. Presented at AMCP Annual Meeting, Apr 2026, and PSI Meeting, Jun 2026 (interim phase 4 data).

Updated Safety & Practice Guidance

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ACOG Clinical Practice Update (Jan 2026)

- Revised guidance on brexanolone and zuranolone for depression with onset in the 3rd trimester through 4 weeks postpartum
- Replaces the August 2023 Practice Advisory

Post-Marketing Safety (FAERS analyses)

- Two independent disproportionality analyses (through 2024 Q2 and 2025 Q1) of FDA adverse event reports
- Sedation: Signals cluster in nervous system (depressed consciousness, mental impairment) and psychiatric disorders
- Isolated 2026 case report of dissociative symptoms
- Caveat: FAERS is passive surveillance (causality cannot be established, no demonitor)
- Long-term data remains limited

Obstet Gynecol. 2026;147(1):e24-e28 (ACOG); Huang D et al. Front Psychiatry. 2025 and additional FAERS analysis through 2025 Q1; Manalai P. Cureus. 2026 (case report).

ACOG Guidance: What Changed, 2023 → 2026

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Brexanolone dropped out of the practical picture

- 2023: recommended as an option. Market-withdrawn Jan 2025; FDA approval formally withdrawn Apr 2025 (cost, complex logistics, strategic shift to oral therapy)

Scope expanded and formalized

- 2023: standalone Practice Advisory on the new approval. 2026: full Clinical Practice Update folded into Guideline No. 5, replacing the 2023 advisory

More candid about evidence limits

- 2026 flags that trials compared zuranolone to placebo only, not SSRIs/psychotherapy, and that no efficacy data exist beyond Day 45

Timeline

- Published online Oct 9, 2025; print issue Jan 2026 — a correction was later issued for Box 1 wording on suicidality monitoring

ACOG Practice Advisory, Aug 2023 (withdrawn) vs. ACOG Clinical Practice Update, Obstet Gynecol. 2026;147(1):e24e28.

ACOG 2026: New Practical Guidance

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Dosing & safety detail (new)

- Structured CNS-effect protocol: hold dose if mild-moderate (sedation, dizziness); resume at 40 mg; discontinue if severe
- CYP3A4 interaction guidance, with specific inhibitor/inducer drug lists
- Lactation data (2024 study): simulated RID <1%, below the 10% compatibility threshold
- Driving-impairment data (2025 study) supports the 12-hour no-driving/no-machinery window
- Schedule IV status confirmed — reinforcing/euphoric effects, barbiturate-like biochemistry

Sharper eligibility guidance

- Trial data support severe symptoms only — suggested thresholds: PHQ-9 ≥20 or EPDS ≥19
- Explicit exclusions: bipolar disorder, psychotic disorders, history of suicide attempt, or active suicidal ideation (all excluded from trials)
- Documented contraceptive plan required before initiation; avoid pregnancy for 1 week post-course
- Can be added to stable SSRI/SNRI therapy — don't empirically stop current antidepressants

Bottom line

- The 2026 update trades a broad new-drug announcement for a narrower, more operational playbook — useful mainly for patients already judged appropriate for zuranolone

ACOG Clinical Practice Update. Obstet Gynecol. 2026;147(1):e24-e28 (published online Oct 9, 2025); erratum Obstet Gynecol 2026.

Get to Patients: Zuranolone

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- Process
  - Send to specific specialty pharmacy
  - Often completing a prior authorization
  - Patient must speak with pharmacy to confirm
- 50 mg nightly taken with fat-containing foods
  - Reduction to 40 mg if not well tolerated
- 14-days
- 12 hours without operating machinery
- Do not need to change other medication, though consider sedating medications*

Get to Patients: Practical Considerations

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- Prior Authorizations, finicky prescribing issues from insurance
- Cost ($15,900)
  - Biogen currently very helpful with coordinating access
- Coordination for patient (receive phone calls, be home to accept)
- Considered a controlled substance
- Collateral support for newborn care (partner, family, doula)

Get to Patients: Zuranolone

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User SmartPhrase – ZURANOLONECLINICIAN [1573438]

ⓘ Do not include PHI or patient-specific data in SmartPhrases.

Insert SmartText | Insert SmartList

Getting Patients started on Zuranolone for Clinicians

I. Considerations and Discussion with Patient_

- **Dose/timing/directions**
  - 50mg daily with evening meal (two 25mg capsules) with fat- containing food (i.e. slice of cheese OR 2 slices of avocado toast OR 2 tbsp of peanut butter) for 14 days.

- **Lactation (RID 0.357%)**
  - LOW amounts of Zuranolone in breast milk, NOT expected to cause adverse effects in breastfed infants.
  - Based on a clinical lactation study from 14 women (12wks or more postpartum) with 30mg indicated LOW levels in breast milk with Zuranolone. No data on effects of Zuranolone on infant and milk production.
  - INFANT MONITORING- particularly for preterm or newborn infants of excessive sedation during breastfeeding. (LactMed 02/2024)

- **Monotherapy or Adjunct**
  - Recommend to NOT start a different medication (particularly a sedative medication) at the same time. This would make it difficult to distinguish which medication is the cause of the side effect.

- **Adverse reactions**
  - Most common were somnolence (36%) , dizziness, diarrhea, fatigue, and urinary tract infection.
    - (Note: CNS depressant effects of intolerable somnolence OR confusional state OR any intolerable side effect REDUCE to 30mg at bedtime)

- **Dose adjustment considerations**
  - AVOID concomitant use with CYP3A4 inducers such as St. John's Wort, glucocorticoids, phenobarbital, phenytoin, or rifampicin.
  - REDUCE to 30mg at bedtime for CYP3A4 inhibitors such as grapefruit/grapefruit juice, seville orange juice, or erythromycin/clarithromycin.
  - REDUCE to 30mg at bedtime for severe hepatic impairment (Child-Pugh C) or moderate to severe renal impairment (eGFR <60)
  - REDUCE to 30mg at bedtime for CNS depressant effects of intolerable somnolence OR confusional state OR any intolerable side effect
  - REDUCE to 30mg at bedtime for unavoidable use with another CNS depressant.

- **Missed dose?**
  - Take the next dose at the regular time the following evening. Do NOT take an extra capsule on the same day to make up for the missed dose. Continue to take Zuranolone in the evening until the remainder of the 14 day treatment course is completed.

- **Warnings and Precautions**
  - Do not drive or engage in potential hazardous activities for at least 12 hours after taking the evening dose. For example, if patient takes their medication at 6pm, recommend to not drive or engage in potential hazardous activities until after 6am the following day.
  - CNS depressant effects such as somnolence and confusion. AVOID other CNS depressants (i.e. alcohol, benzodiazepines, TCA, or opioids) as they may INCREASE impairment of psychomotor performance/falls/respiratory depression.
  - Embryo-fetal toxicity was found in animal studies. Advise pregnant women of risk/recommend to use effective contraception during treatment with Zuranolone and for one week after the final dose.

Get to Patients: Zuranolone

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Do not include PHI or patient-specific data in SmartPhrases.

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II. Prescribing through EPIC

- **STEP 1- Search for medication**
  - In orders, SEARCH for Zuranolone, CLICK on "database", SELECT correct dose.
- **STEP 2- Link with diagnosis/F code AND add note to pharmacy**
  - CLICK on Zuranolone, in the Zuranolone medication window, CHANGE frequency to daily with evening meal (write this in, it won't pop up but it will update the patient sig, ADD 14 to the duration (14 days), CLICK on "Note to Pharmacy" WRITE in "F53 Postpartum depression, pt phone number XXX XXX XXXX" (do not add a period in this field), CLICK on "Additional Order Details", SELECT postpartum depression
- **STEP 3- Choose correct pharmacy**
  - Send to a Speciality Pharmacy. I recommend to first start with Walmart Speciality Pharmacy if it's not specifically noted below. If it's not the correct speciality pharmacy for the patient's insurance, a fax will be prompted and sent to the clinic to prescribe the medication to a different speciality pharmacy.
  - CLICK on the pharmacy, SEARCH by name or phone number, SELECT correct pharmacy, CLICK on "accept"
    - Walmart Speciality Pharmacy- 877.453.4566
      - Aetna, Anthem, BCBS Federal Employee Program, Express Scripts, Molina, Cigna, NC Medicaid Wellcare
    - Accredo- 800.272.3858
      - Express scripts, BCBS Federal Employee Program, Centene Plans, Cigna, Health care service Corporation (BCBS of Illinois/Montana/New Mexico/Oklahoma/Texas), Prime therapeutics/Magellan, Tricare, UnitedHealthCare/Optum, UnitedHealthCare, Optum
    - Alto Pharmacy- 800.874.5881
      - UnitedHealthCare/Optum
    - CVS Speciality- 866.993.4779
      - Aetna, Anthem, BlueShield or Blue Cross of CA, Florida Blue, CVS Caremark
- **STEP 4- Sign orders**
  - CLICK on sign orders
- **STEP 5- Alert patient**
  - Important- tell the patient that the pharmacy will call them to confirm insurance and contact information. I have recommended for patient's to add the pharmacy's phone number (up above) to their phone so that they will answer the call.
    - Specific to Walmart- you can alternatively, have the patient call the pharmacy and ask to speak with their "high touch department". The pharmacy will create the patient's profile, obtain all the necessary information, and obtain consent for copay assistance.
    - Specific to Accredo, select option 5 to talk to the correct department
  - Note: A prior authorization or an appeal will be generated after this step. Complete this as appropriate.
- **STEP 6- Medication will be sent to patient**

Have questions? Zuranolone representatives are available to discuss process- 1.844.987.9882

III. Documentation- Consent

- Discussed risk/benefits/alternatives to zuranolone including boxed warning for impaired ability to drive or engage in other potential hazardous activities for at least 12 hours after taking the medication. Discussed common side effects of somnolence, dizziness, diarrhea, fatigue, and urinary tract infection. Discussed importance of avoiding other CNS depressants such as alcohol, opioids, or benzodiazepines. Patient voiced understanding and provided consent to this treatment for postpartum depression.

IV. Patient Education

- **What should I know?**
  - Zuranolone can cause decreased awareness and alertness particularly the 12 hours after taking the medication.
  - It may cause sleepiness, drowsiness, slow thinking, confusion, and trouble walking. Because of these symptoms you may be at a higher risk for falls.
  - Taking alcohol, opioids, or benzodiazepines can worsen the decreased awareness and alertness side effect, and may also cause trouble breathing.
  - Tell your provider if you have any of these symptoms. They may decrease or stop treatment with zuranolone.
- **Missed dose?**
  - Take the next dose at the regular time the following evening. Do NOT take an extra capsule on the same day to make up for the missed dose. Continue to take Zuranolone in the evening until the remainder of the 14 day treatment course is completed.
- **When will it start working? Does the improvement go away?**
  - As early as 3 days. Improvement was sustained for at least 4 weeks.

In Research at UNC...

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UNC Research: Brexanolone's Immune Signature

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Balan et al., Translational Psychiatry (2026)

- 10 women with PPD, followed to Day 30 post-brexanolone (14 immune/neurotrophic markers)
- CCL11 and IL-6 durably suppressed; BDNF rose and stayed elevated through Day 30
- Same durable effect held under TLR4 challenge — immune cells were functionally "recalibrated," not just resting quieter
- Biomarker changes tracked with HAM-D improvement over time

Why it matters for zuranolone

- Its D-ring modification (built for oral bioavailability) may weaken this same TLR-immune engagement — a plausible driver of its more variable real-world response

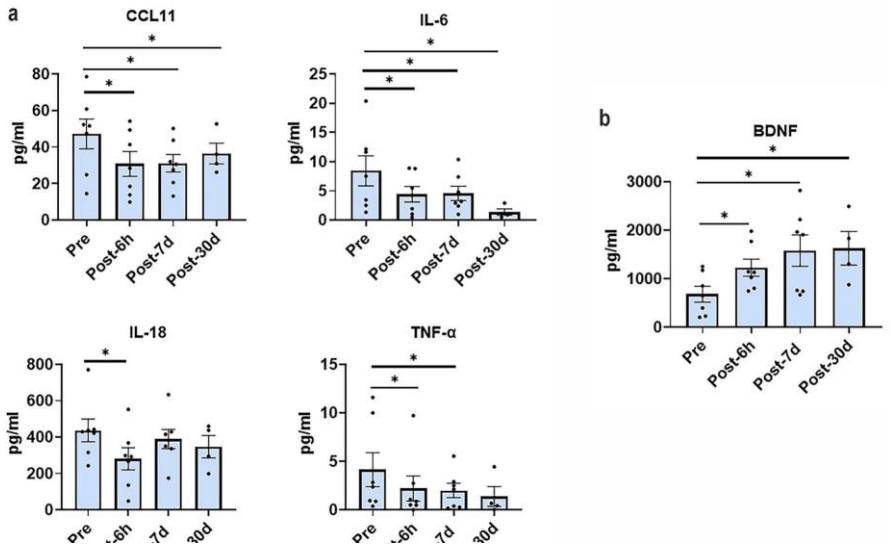

*Fig. 1: CCL11, IL-6, and IL-18 fall while BDNF rises after brexanolone infusion, tracked through Day 30 (n=10, mean ± SEM, *FDR-adj p≤0.05).*

Balan I et al. Transl Psychiatry. 2026;16:119. Builds on Balan I et al. eBioMedicine. 2023;89:104473.

What's Next: Zuranolone + Pregnenolone

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Pregnenolone Augmentation of Zuranolone for Postpartum Depression: Restoring the Immunoregulatory Mechanism

UNC pilot study (Riddle, PI) — supported by a UNC Junior Faculty Development Award and a BBRF Young Investigator Award

The question

- Pregnenolone is a neurosteroid precursor with anti-inflammatory activity independent of GABAergic signaling — can it restore the immune-neurotrophic signature seen with brexanolone when added to zuranolone?

Design (pilot)

- N=20 postpartum women starting zuranolone: 10 zuranolone alone vs. 10 zuranolone + pregnenolone
- Whole-blood immune/neurotrophic biomarkers at baseline and Day 14; HAM-D followed through Day 90

IRB review underway — launch imminent

Riddle JN. UNC Junior Faculty Development Award & BBRF Young Investigator Award; BIRCWH K12 application, 2026.

Future Directions: Question

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- Prevention of PPD in high-risk patients?
- Role in postpartum anxiety, bipolar disorder, psychosis, and other disorders?
- Mechanistic understanding?
- Can these be utilized in premenstrual dysphoric disorder (PMDD), premenstrual exacerbation (PME), and perimenopause mood symptoms?

Also in Research...

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Other Modalities

- Psilocybin in the postpartum (RE104)
- TMS/tACS
- Ketamine?

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Thank you!

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