Trileptal

(oxcarbazepine)

Trileptal (oxcarbazepine); not controlled

Full Prescribing Information	DailyMed Drug Information

Summary

Trileptal is a sodium channel blocking antiepileptic, supplied as tablets and oral suspension, approved only for partial seizures: monotherapy from 4 years, adjunctive from 2 years. It carries no psychiatric indication at any age, so use for aggression, mood dysregulation or impulse control is entirely off-label. Its defining safety issue is hyponatremia, common enough to require scheduled sodium checks. Not controlled; brand and generic.

Forms & Strengths

- **Tablets:** 150 mg, 300 mg, 600 mg
- **Oral suspension:** 300 mg/5 mL
- **Extended-release tablets:** 150 mg, 300 mg, 600 mg

Dosing

- **Age:**
  - Partial seizures, monotherapy: 4 y/o and older
  - Partial seizures, adjunctive: 2 y/o and older
  - Psychiatric and behavioural use: no approved age; entirely off-label
- **Onset:** 2 to 4 weeks, the time titration takes to reach target
- **Duration:** continuous with twice-daily dosing
- **Initial Dose:**
  - Pediatric monotherapy, 4 to 16 y/o: 8 to 10 mg/kg/day in two divided doses

    - Pediatric adjunctive, 2 to 16 y/o: 8 to 10 mg/kg/day divided, generally not above 600 mg/day
    - Under 20 kg: 16 to 20 mg/kg/day may be considered
    - Adults, all uses: 600 mg/day in two divided doses
- **Titration:**
    - Pediatric monotherapy initiation: 5 mg/kg/day every 3 days
    - Pediatric conversion to monotherapy: up to 10 mg/kg/day weekly
    - Pediatric adjunctive: reach target over 2 weeks, or 2 to 4 weeks under 4 y/o
    - Adults: up to 600 mg/day weekly; 300 mg/day every third day for monotherapy
- **Max Dose:**
    - Pediatric adjunctive, 2 to under 4 y/o: 60 mg/kg/day
    - Adjunctive 4 to 16 y/o: 900 mg/day at 20 to 29 kg, 1200 mg/day at 29.1 to 39 kg, 1800 mg/day above 39 kg
    - Monotherapy maintenance: 600 to 900 mg/day at 20 kg, up to 1500 to 2100 mg/day at 70 kg
    - Adults: 2400 mg/day, which most patients cannot tolerate
- **Considerations:** All dosing is twice daily. Halve the starting dose to 300 mg/day and titrate slowly if creatinine clearance is under 30 mL/min; no adjustment for mild to moderate hepatic impairment.

Pharmacology

- **Mechanism:** Blocks voltage-gated sodium channels, stabilising hyperexcited membranes; no demonstrated interaction with brain neurotransmitter or modulator receptors
- **Delivery / Release:** immediate-release, completely absorbed, median Tmax 4.5 hours; with or without food
- **Metabolism:** prodrug converted to the active 10-monohydroxy derivative (MHD); half-life 2 hours parent, 9 hours MHD, 19 hours if creatinine clearance is under 30 mL/min
- **Pharmacogenomics:** HLA-B*1502 carriers risk Stevens-Johnson syndrome and toxic epidermal necrolysis. Test before starting in at-risk ancestry; avoid unless benefit clearly outweighs risk.
- **Class Positioning:** like carbamazepine but with much less enzyme induction; hyponatremia is more frequent, not less. Adjunct to an ADHD regimen (Concerta, Strattera, Qelbree), never a replacement.

Indications

- **Partial Seizures, monotherapy** (ICD-10: G40.1, G40.2): patients 4 y/o and older, and adults
- **Partial Seizures, adjunctive therapy** (ICD-10: G40.1, G40.2): patients 2 y/o and older, and adults

- No other approved indication exists, psychiatric or otherwise, at any age.

Off-Label Uses

- **Aggression, irritability and mood dysregulation** (ICD-10: F90.x, F91.x): limited data. Risperidone (Risperdal) has moderate graded evidence here; oxcarbazepine has none. (AHRQ 2017)
- **Where the evidence does not support use:**
  - **Pediatric bipolar disorder** (ICD-10: F31.x): insufficient; the carbamazepine analogy is pharmacological, not evidential.
  - **Neuropathic pain, trigeminal neuralgia** (ICD-10: G50.0, M79.2): insufficient; no pain indication at any age.
  - **Generalized seizures** (ICD-10: G40.3): insufficient and potentially harmful; can worsen some generalized epilepsies.

Contraindications & Warnings

- **Class warning, suicidal behaviour and ideation:** antiepileptics roughly double the risk (adjusted RR 1.8, 95% CI 1.2 to 2.7), from week one, in every indication.
- **Contraindicated:** known hypersensitivity to oxcarbazepine or any component.
- **Use with caution:**
  - Prior carbamazepine hypersensitivity: 25% to 30% cross-react. Ask directly.
  - Ancestry in a high HLA-B*1502 frequency population, for Stevens-Johnson syndrome and toxic epidermal necrolysis risk.
  - Any other sodium-lowering drug: thiazides, SNRIs, drugs causing inappropriate ADH secretion.
  - Creatinine clearance under 30 mL/min: halve the starting dose; MHD half-life roughly doubles.
  - Hormonal contraception in an adolescent, because oxcarbazepine reduces its effectiveness.
  - Pregnancy or possible pregnancy, because oxcarbazepine is likely a human teratogen.
- **Screen before starting:**
  - Baseline serum sodium; a later result cannot be interpreted without it.
  - Prior reaction to carbamazepine, asked as a direct question.
  - Ancestry, to decide whether HLA-B*1502 testing is indicated first.
  - Renal function; the medication list for sodium-lowering drugs and hormonal contraception.
  - Baseline mood and any history of suicidal ideation.

Drug Interactions

- **Hormonal contraceptives** (oral, patch, ring): effectiveness is reduced. Arrange an alternative or added method before the first dose.
- **Other antiepileptics** (carbamazepine, phenytoin, phenobarbital): mutual changes in exposure above 1200 mg/day. Check their levels through titration and at any dose change.
- **Calcium antagonists** (felodipine, verapamil): exposure is altered. Recheck blood pressure after any change.
- **Other sodium-lowering drugs** (thiazides, SSRIs, SNRIs, desmopressin, carbamazepine): additive hyponatremia. Check sodium 2 to 4 weeks after starting and at any dose change.
- **Laboratory tests:** T4 falls without T3 or TSH change. Read an isolated low T4 as a drug effect, not hypothyroidism.

Administration

- Give twice daily at roughly 12-hour intervals. The extended-release oxcarbazepine product is a separate NDA and must not be substituted milligram for milligram.
- May be taken with or without food.
- Use the oral suspension for weight-based pediatric dosing rather than splitting tablets.
- The suspension is 60 mg/mL: divide the milligram dose by 60 for millilitres.
- Shake the suspension; measure with a calibrated oral syringe, never a kitchen spoon.
- Do not stop abruptly. See Discontinuation & Taper.

Side Effects

- **Common** (at least 5%, above placebo): dizziness, somnolence, diplopia, fatigue, nausea, vomiting, ataxia, abnormal vision, abdominal pain, tremor, dyspepsia, abnormal gait
- **Serious:**
  - Hyponatremia: sodium below 125 mmol/L in 2.5% of treated patients, usually asymptomatic. Reduce the dose or stop.
  - Anaphylaxis and angioedema of the larynx, glottis, lips or eyelids: stop and never rechallenge.
  - Stevens-Johnson syndrome and toxic epidermal necrolysis, median onset 19 days. Stop for any rash.
  - DRESS: fever, rash or lymphadenopathy with organ involvement. Discontinue unless another cause is established.
  - Dose-related psychomotor slowing, impaired concentration, speech problems, ataxia and gait disturbance.
  - Pancytopenia, agranulocytosis and leukopenia, rare: consider discontinuation.

Monitoring & Labs

- **Serum sodium:** baseline, 2 to 4 weeks after starting, after every dose increase, at 3 months, then at least every 6 months; also 2 to 4 weeks after adding any sodium-lowering drug.
- **Serum sodium, unscheduled:** for nausea, malaise, headache, lethargy, confusion, obtundation, or rising seizure frequency. Act before 125 mmol/L.
- **Suicidality and mood:** at 1 week, 1 month, every dose change, and each routine visit thereafter.
- **Skin:** ask about rash at every visit for the first 3 months; the family reports any rash the same day.
- **Cognitive and motor function:** ask family and school about concentration, sleepiness and falls at each dose increase and every 6 months.
- **Contraception review:** every visit, in any adolescent who could become pregnant.

Discontinuation & Taper

- **Withdraw gradually**, per the label, to minimise increased seizure frequency. This holds even for off-label behavioural use.
- Converting to another antiepileptic: withdraw over 3 to 6 weeks while the replacement reaches target over 2 to 4 weeks.
- Stop permanently, no rechallenge, for anaphylaxis, angioedema or any serious dermatological reaction.
- Discontinue for DRESS unless an alternative cause is established.
- Reduce or stop for clinically significant hyponatremia; sodium normalises within a few days.
- Drug holidays are not appropriate for either use.

Pregnancy & Lactation

- **Pregnancy:** No adequate controlled studies; the label states oxcarbazepine is likely a human teratogen. Use only if benefit justifies risk.
- **Pregnancy, dosing:** plasma MHD falls through pregnancy and returns after delivery; monitor seizure control across pregnancy and postpartum.
- **Lactation:** milk-to-plasma ratio 0.5; levels low, adverse effects not expected beyond 2 months. Monitor infant drowsiness, weight gain, milestones. (LactMed 2024)
- **Exposure Registry:** North American Antiepileptic Drug Pregnancy Registry, 1-888-233-2334; the patient enrolls herself.

Counseling Points

- **Counsel the family on:**
  - This being a seizure medicine; behavioural use is off-label, with no approved dose ladder.
  - The sodium blood test schedule, done even when the child feels well; most affected children have no symptoms.
  - Reporting any rash the same day; name blistering, peeling and mouth or eye sores.
  - Sleepiness, unsteadiness and double vision being dose-related; report after an increase.
  - Never stopping suddenly, even if it seems to be doing nothing: that can trigger seizures.
  - For an adolescent who could become pregnant: less reliable hormonal birth control, likely fetal harm.
- **Advise them to call for:**
  - Blistering or peeling skin, or mouth, eye or genital sores, immediately.
  - Swelling of the lips, tongue, eyelids or throat, or trouble breathing.
  - Fever with swollen glands, with or without rash.
  - Headache with unusual sleepiness, confusion, unsteadiness, or more frequent seizures.
  - New or worsening talk of self-harm, or a sudden mood change.
  - Unusual bruising, bleeding, or repeated infections.

References

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Revision #23
Created 2024-12-31 06:42:42 UTC by Josh LeJeune NP
Updated 2026-08-20 06:40:15 UTC by Josh LeJeune NP