

Topamax (topiramate)

Generic name: Topiramate

Available strengths: 25 mg, 50 mg, 100 mg,

200 mg capsules and tablets;

15 mg, 25 mg sprinkle capsules (Topamax Sprinkle) Available in generic: Yes, except Topamax Sprinkle

Drug class: Anticonvulsant/mood stabilizer

General Information

Topamax (topiramate) is better known for its use as an anticonvulsant—a medication for treating epilepsy. This may present some confusion for patients, as well as their families, when they are prescribed Topamax without a history of seizures. Topamax was first approved by the U.S. Food and Drug Administration for the treatment of epilepsy and, recently, for prophylaxis of migraine headache. The use of a medication for its approved indications is called its *labeled use*. In clinical practice, however, physicians often prescribe medications for *unlabeled* ("off-label") uses when published clinical studies, case reports, or their own clinical experiences support the efficacy and safety of those treatments. The use of Topamax for treatment of bipolar disorder, particularly in acute mania, is an example of its off-label use. Other conditions for which Topamax is commonly used off-label include eating disorders (e.g., binge eating and bulimia) and alcohol and cocaine withdrawal.

Preliminary clinical studies suggest that Topamax may be effective when used in conjunction with another mood stabilizer for treatment of bipolar disorder in both the manic and depressive phases. The advantage of Topamax over some other mood stabilizers, such as Depakote, is that it does not induce weight gain but rather can produce mild weight loss. When Topamax is used in combination therapy, it can counteract the side effect of weight gain of another mood stabilizer and provide mood stabilization as well.

Dosing Information

Topamax is usually started at a dosage of 12.5–25 mg/day, and the dosage is increased by 25 mg a week. Average dosages for mood stabilization are usually 100–200 mg/day given in divided doses. Dosage should not exceed the usual maximum of 400 mg/day.

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Common Side Effects

The most common side effects associated with Topamax are somnolence, fatigue, impaired coordination, difficulty with walking (**ataxia**), difficulty with concentration and attention, and gastrointestinal symptoms, including nausea, vomiting, and abdominal cramping. Generally, these side effects are more frequent and intense at higher dosages.

Adverse Reactions and Precautions

Topamax may cause drowsiness and impair alertness, especially at the start of therapy. Patients should use caution when driving or performing tasks that require alertness.

Kidney Stones

A total of 1.5% of patients treated with Topamax experienced kidney stones. The risk of kidney stones appeared to be higher in men treated with Topamax. By increasing fluid intake to promote urine output, the risk of kidney stone formation may be decreased.

Central Nervous System

Central nervous system–related adverse reactions with Topamax include mental and physical slowing, difficulty with concentration, dizziness or imbalance, confusion, and irritability. Seniors may be particularly susceptible to losing their balance and falling.

Metabolic Acidosis

Topamax can induce an electrolyte imbalace and cause a condition called **metabolic acidosis**. This adverse reaction is generally rare, but patients with renal disease, severe respiratory disease, chronic diarrhea, or other medical conditions may be more susceptible to Topamax. The clinical signs of metabolic acidosis include rapid respiration on resting, nonspecific symptoms such as tiredness and loss of appetite, and rapid heart rate. Patients should report any of these symptoms to their physician. A laboratory test to measure the serum bicarbonate level can help diagnose metabolic acidosis.

Use in Pregnancy and Breastfeeding: Pregnancy Category C

There are no adequate controlled studies of Topamax in pregnant women to determine the medication's risk to the woman and fetus. However, Topamax may have potential risks in humans because it has been associated with fetal malformations in animal studies. The use of Topamax should be avoided in pregnancy whenever possible, especially in the first trimester. However, if Topamax is required because stopping the medication may result in relapse and present a greater danger to the mother and unborn child, the patient may continue to take Topamax, after giving informed consent to the physician, or an alternative medication or treatment may be used.

It is not known if Topamax is excreted in human breast milk. However, nursing mothers should not take Topamax. If stopping the medication is not an alternative, breastfeeding should not be started or should be discontinued.

Possible Drug Interactions

When Topamax is combined with other medications, it may alter their metabolism and the blood levels of these medications. When the levels are lowered, it may decrease the medication's effectiveness; conversely, when levels are elevated, the person may become susceptible to the medication's toxic effects. Other medications may similarly affect the blood levels of Topamax. The clinically significant drug interactions reported with Topamax are summarized in the table below.

| Estrogens in oral contraceptives | When Topamax is taken in combination with oral contraceptives containing estrogen, the level of estrogen may be lowered, decreasing the effectiveness of the contraceptive and perhaps resulting in an unplanned pregnancy. |
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| Tegretol (carbamazepine) | Topamax concentrations may be decreased significantly if it is used with Tegretol, decreasing Topamax's effectiveness. |
| Dilantin (phenytoin) | Topamax concentrations may be decreased significantly if it is used with Dilantin, decreasing Topamax's effectiveness. |
| Diamox (acetazolamide) and other carbonic anhydrase inhibitors | Combination of Topamax with medications known as carbonic anhydrase inhibitors, such as Diamox, may increase the risk of renal stones and should be avoided. |

Patients taking Topamax should not consume alcohol because the combination may increase sedation and drowsiness. Moreover, the sedative effects of alcohol may act as a depressant, obscuring the therapeutic effects of Topamax and complicating treatment.

Overdose

Depending on the amount ingested, overdose with Topamax can be serious. Non-life-threatening symptoms of overdose include dizziness, ataxia (impaired coordination while walking), headache, and somnolence. In severe cases, overdose may result in delirium, liver and renal failure, and coma.

Any suspected overdose should be treated as an emergency. The person should be taken to the emergency room for observation and treatment. The prescription bottle of medication (and any other medication suspected in the overdose) should be brought as well, because the information on the prescription label can be helpful to the treating physician in determining the number of pills ingested.

Special Considerations

• If you miss a dose, take it as soon as possible, within 2–3 hours of the scheduled dose. If it is close to the next scheduled dose, skip the missed dose and continue on your regular dosing schedule. Do not take double doses.

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- Take Topamax immediately after meals or with food to decrease stomach upset.
- Maintain an adequate fluid intake to minimize the risk of kidney stone formation, especially if you are predisposed to kidney stones.
- Topamax may cause sedation and drowsiness, especially during initiation of therapy, and impair your alertness. Use caution when driving or performing tasks that require alertness.
- Store the medication in its originally labeled, light-resistant container, away from heat and moisture. Heat and moisture may precipitate breakdown of your medication, and the medication may lose its therapeutic effects.
- Keep your medication out of reach of children.

If you have any questions about your medication, consult your physician or pharmacist.

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