

## **Topamax (topiramate) General Information**

*Weight No More – Effective, physician-supervised weight-management solutions*  
Newport Beach (949) 645-2930 Temecula (951) 699-0848

- Main Indication For Use:** Migraine prevention and as adjunctive therapy in children and adults with partial onset seizures or primary generalized tonic-clonic seizures.
- Side Effects:** Most common and not dose related were somnolence (sleepiness,) dizziness, ataxia (loss of balance,) psychomotor slowing, difficulty with memory, paresthesias (numbness and tingling sensation involving extremities,) “metallic” taste in mouth.
- Dose Related Side Effects:** Include fatigue, nervousness, and difficulty with concentration, anorexia, weight decrease.
- General Precautions:** Increased incidence of kidney stones (1.5%) = @ 2-4 times expected at doses above 300mg/day. Higher in men vs. women. High fluid intake to prevent dehydration should decrease this risk.
- Do not use with diamox (acetazolamide,) or in conjunction with a ketogenic (starvation type) diet.
- How Supplied:** Topamax is in tablet/pill form (25/50/200 mgs)
- Dosage – Take in the evening**
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| <b>Week 1:</b> | <b>25mg samples (1)</b>                    |
| <b>Week 2:</b> | <b>¼ of 200mg tab = 50mg</b>               |
| <b>Week 3:</b> | <b>¼ of 200mg tab + 25mg sample = 75mg</b> |
| <b>Week 4:</b> | <b>½ of 200mg tab = 100mg</b>              |
- Additional Information:** Topamax has been used in over 1 million patients and has been on the market for 8 years. The “off label” use of Topamax for chronic pain syndromes, bipolar illness and obsessive compulsive disorders, exceeds its “on label” indication as adjunctive treatment for partial complex seizures.
- Topamax has been used safely down to the age of two.
- Johnson and Johnson are currently conducting studies evaluating Topamax as a weight loss medication. Possible FDA approval in 2 – 3 years.
- Important Notes:** Topamax may decrease the effectiveness of oral contraceptives; therefore alternative birth control methods are recommended.
- If confusion or disorientation occurs, discontinue Topamax (regardless of dose) and contact my office immediately.
- If your “distant” vision seems to get worse during the first six weeks of treatment, discontinue and contact my office as soon as possible. (23 case reports from a database of 825,000.)

### **ADDENDUM TO “APPETITE SUPPRESSANT INFORMED CONSENT”**

I have read and understand my doctor’s statements regarding the use of Topamax (topiramate) and its “off label” use for medical weight loss.

I have been fully informed of the increased risk of kidney stones. I will report any adverse side effects to my physician including, but not limited to, somnolence, fatigue, dizziness, nervousness, etc.

I am aware that I will be taking Topamax (topiramate) as an adjunct to appetite suppressant medication and/or antidepressant medication. I will be monitored on a monthly basis or more frequently as medically indicated.

I have had an opportunity to ask questions and have them answered to my satisfaction.

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Patient’s Signature / Date

\_\_\_\_\_  
Physician’s Signature

## **TOPAMAX (topiramate) SAFETY INFORMATION**

An effective treatment option for migraine prevention.

TOPAMAX Tablets and TOPAMAX Sprinkle Capsules are indicated for adults for the prophylaxis of migraine headache. The usefulness of TOPAMAX in the acute treatment of migraine headache has not been studied.

### **Important Safety Information**

TOPAMAX is contraindicated in patients with a history of hypersensitivity to any component of this product.

The most common adverse event was paresthesia (defined as tingling in the extremities); however, severity was mild to moderate and discontinuation due to this effect was 7%.

Most common adverse events associated with TOPAMAX 100mg vs. placebo were: paresthesia, 51% vs. 6%; anorexia (loss of appetite),\* 15% vs. 6%; fatigue, 15% vs. 11%; nausea, 13% vs. 8%; diarrhea, 11% vs. 4%; weight decrease, 9% vs. 1%; taste alteration, 8% vs. 1%.

Of the 1135 patients exposed to topiramate in the placebo-controlled studies, 25% discontinued due to adverse events, including:

- ? Hyperchloremic, non-anion gap metabolic acidosis lowering of bicarbonate levels in the blood. Measurement of baseline and periodic serum bicarbonate is recommended.
- ? Acute myopia and secondary angle-closure glaucoma-patients should be cautioned to seek medical attention if they experience blurred vision or ocular pain.
- ? Oligohidrosis and hyperthermia-decreased sweating and increased body temperature, especially in hot weather. The majority of reports have been in children.
- ? Cognitive/psychiatric side effects including cognitive dysfunction, psychiatric/behavioral disturbances, and somnolence and fatigue.

The possibility of decreased contraceptive efficacy and increased breakthrough bleeding should be considered in patients taking combination oral contraceptive products with TOPAMAX.

Patients should be instructed to maintain an adequate fluid intake in order to minimize the risk of renal stone formation.