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TOPAMAX
(topiramate) Tablets

Topamax

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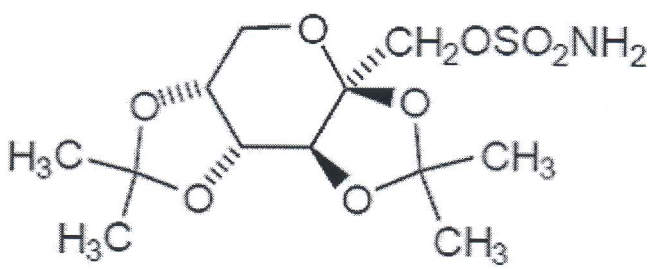
DRUG DESCRIPTION

Topiramate is a sulfamate-substituted monosaccharide. TOPAMAX® (topiramate) Tablets are available as 25 mg, 50 mg, 100 mg, and 200 mg round tablets for oral administration. TOPAMAX® (topiramate capsules) Sprinkle Capsules are available as 15 mg and 25 mg sprinkle capsules for oral administration as whole capsules or opened and sprinkled onto soft food.

Topiramate is a white crystalline powder with a bitter taste. Topiramate is most soluble in alkaline solutions containing sodium hydroxide or sodium phosphate and having a pH of 9 to 10. It is freely soluble in acetone, chloroform, dimethylsulfoxide, and ethanol. The solubility in water is 9.8 mg/mL. Its saturated solution has a pH of 6.3. Topiramate has the molecular formula $C_{12}H_{21}NO_8S$ and a molecular weight of 339.36. Topiramate is designated chemically as 2,3:4,5Di-O-isopropylidene-β-D-fructopyranose sulfamate and has the following structural formula:



TOPAMAX® Tablets contain the following inactive ingredients: carnauba wax, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, purified water, sodium starch glycolate, synthetic iron oxide, and titanium dioxide.

TOPAMAX® Sprinkle Capsules contain topiramate-coated beads in a hard gelatin capsule. The inactive ingredients are sugar spheres (sucrose and starch), povidone, cellulose acetate, gelatin, sorbitan monolaurate, sodium lauryl sulfate, titanium dioxide, and black pharmaceutical ink.

What are the possible side effects of topiramate (Topamax, Topamax Sprinkle, Topiragen)?

Get emergency medical help if you have any of these **signs of an allergic reaction:** hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Report any new or worsening symptoms to your doctor, such as: mood or behavior changes, anxiety, panic attacks, trouble sleeping, or if you feel impulsive, irritable, agitated, hostile, aggressive, restless, hyperactive (mentally or physically), more depressed, or have thoughts about suicide or hurting yourself.

Call your doctor at once if you have a serious side effect such...

Read All Potential Side Effects and See Pictures of Topamax »

What are the precautions when taking topiramate (Topamax)?

Before taking topiramate, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: a certain eye problem (narrow angle glaucoma), kidney problems (such as kidney stones), liver problems, mental/mood problems (such as depression, thoughts of suicide), lung/breathing problems, a certain metabolic imbalance (metabolic acidosis), long-term diarrhea, a diet high in fat and low in carbohydrates (ketogenic diet), brittle bones (osteoporosis).

This drug may make you dizzy or drowsy or impair your judgment....

Read All Potential Precautions of Topamax »

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Pharmacy Editor: Eni Williams, PharmD, PhD

This monograph has been modified to include the generic and brand name in many instances.

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INDICATIONS

Monotherapy Epilepsy

TOPAMAX®(topiramate) Tablets and TOPAMAX®(topiramate capsules) Sprinkle Capsules are indicated as initial monotherapy in patients 2 years of age and older with partial onset or primary generalized tonic-clonic seizures. Safety and effectiveness in patients who were converted to monotherapy from a previous regimen of other anticonvulsant drugs have not been established in controlled trials [see **Clinical Studies**].

Adjunctive Therapy Epilepsy

TOPAMAX® Tablets and TOPAMAX® Sprinkle Capsules are indicated as adjunctive therapy for adults and pediatric patients ages 2 to 16 years with partial onset seizures or primary generalized tonic-clonic seizures, and in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome [see **Clinical Studies**].

Migraine

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

DOSAGE AND ADMINISTRATION

Epilepsy

It is not necessary to monitor topiramate plasma concentrations to optimize TOPAMAX® (topiramate) therapy.

On occasion, the addition of TOPAMAX® to phenytoin may require an adjustment of the dose of phenytoin to achieve optimal clinical outcome. Addition or withdrawal of phenytoin and/or carbamazepine during adjunctive therapy with TOPAMAX® may require adjustment of the dose of TOPAMAX®.

Because of the bitter taste, tablets should not be broken.

TOPAMAX® can be taken without regard to meals.

Monotherapy Use

Adults and Pediatric Patients 10 Years and Older

The recommended dose for TOPAMAX® monotherapy in adults and pediatric patients 10 years of age and older is 400 mg/day in two divided doses. Approximately 58% of patients randomized to 400 mg/day achieved this maximal dose in the monotherapy controlled trial; the mean dose achieved in the trial was 275 mg/day. The dose should be achieved by titration according to the following schedule (Table 1):

Table 1: Monotherapy Titration Schedule for Adults and Pediatric Patients 10 years and older

	Morning Dose	Evening Dose
Week 1	25 mg	25 mg
Week 2	50 mg	50 mg
Week 3	75 mg	75 mg
Week 4	100 mg	100 mg
Week 5	150 mg	150 mg
Week 6	200 mg	200 mg

Children Ages 2 to < 10 Years

Dosing of topiramate as initial monotherapy in children 2 to < 10 years of age with partial onset or primary generalized tonic-clonic seizures was based on a pharmacometric bridging approach [see Clinical Studies].

Dosing in patients 2 to < 10 years is based on weight. During the titration period, the initial dose of TOPAMAX® should be 25 mg/day administered nightly for the first week. Based upon tolerability, the dosage can be increased to 50 mg/day (25 mg twice daily) in the second week. Dosage can be increased by 25-50 mg/day each subsequent week as tolerated. Titration to the minimum maintenance dose should be attempted over 5-7 weeks of the total titration period. Based upon tolerability and seizure control, additional titration to a higher dose (up to the maximum maintenance dose) can be attempted at 25-50 mg/day weekly increments. The total daily dose should not exceed the maximum maintenance dose for each range of body weight (Table 2).

Table 2: Monotherapy Target Total Daily Maintenance Dosing for Patients 2 to < 10 Years

Weight (kg)	Total Daily Dose (mg/day) * Minimum Maintenance Dose	Total Daily Dose (mg/day) * Maximum Maintenance Dose
Up to 11	150	250
12 - 22	200	300
23 - 31	200	350
32 - 38	250	350
Greater than 38	250	400

* Administered in two equally divided doses

Adjunctive Therapy Use

Adults 17 Years of Age and Over - Partial Onset Seizures, Primary Generalized Tonic-Clonic Seizures, or Lennox-Gastaut Syndrome

The recommended total daily dose of TOPAMAX® as adjunctive therapy in adults with partial onset seizures is 200 to 400 mg/day in two divided doses, and 400 mg/day in two divided doses as adjunctive treatment in adults with primary generalized tonic-clonic seizures. It is recommended that therapy be initiated at 25 to 50 mg/day followed by titration to an effective dose in increments of 25 to 50 mg/day every week. Titrating in increments of 25 mg/day every week may delay the time to reach an effective dose. Doses above 400 mg/day (600, 800 or 1,000

mg/day) have not been shown to improve responses in dose-response studies in adults with partial onset seizures. Daily doses above 1,600 mg have not been studied.

In the study of primary generalized tonic-clonic seizures, the initial titration rate was slower than in previous studies; the assigned dose was reached at the end of 8 weeks [see Clinical Studies].

Pediatric Patients Ages 2 - 16 Years – Partial Onset Seizures, Primary Generalized Tonic-Clonic Seizures, or Lennox-Gastaut Syndrome

The recommended total daily dose of TOPAMAX® as adjunctive therapy for pediatric patients with partial onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 to 9 mg/kg/day in two divided doses. Titration should begin at 25 mg/day (or less, based on a range of 1 to 3 mg/kg/day) nightly for the first week. The dosage should then be increased at 1- or 2-week intervals by increments of 1 to 3 mg/kg/day (administered in two divided doses), to achieve optimal clinical response. Dose titration should be guided by clinical outcome.

In the study of primary generalized tonic-clonic seizures, the initial titration rate was slower than in previous studies; the assigned dose of 6 mg/kg/day was reached at the end of 8 weeks [see **Clinical Studies**].

Migraine

The recommended total daily dose of TOPAMAX® as treatment for adults for prophylaxis of migraine headache is 100 mg/day administered in two divided doses (Table 3). The recommended titration rate for topiramate for migraine prophylaxis to 100 mg/day is:

Table 3: Migraine Prophylaxis Titration Schedule for Adults

	Morning Dose	Evening Dose
Week 1	None	25 mg
Week 2	25 mg	25 mg
Week 3	25 mg	50 mg
Week 4	50 mg	50 mg

Dose and titration rate should be guided by clinical outcome. If required, longer intervals between dose adjustments can be used.

TOPAMAX® can be taken without regard to meals.

Administration Of TOPAMAX®Sprinkle Capsules

TOPAMAX® (topiramate capsules) Sprinkle Capsules may be swallowed whole or may be administered by carefully opening the capsule and sprinkling the entire contents on a small amount (teaspoon) of soft food. This drug/food mixture should be swallowed immediately and not chewed. It should not be stored for future use.

Patients With Renal Impairment

In renally impaired subjects (creatinine clearance less than 70 mL/min/1.73 m^2), one-half of the usual adult dose is recommended. Such patients will require a longer time to reach steady-state at each dose.

Geriatric Patients (Ages 65 Years and Over)

Dosage adjustment may be indicated in the elderly patient when impaired renal function (creatinine clearance rate < 70 mL/min/1.73 m^2) is evident [see **CLINICAL PHARMACOLOGY**].

Patients Undergoing Hemodialysis

Topiramate is cleared by hemodialysis at a rate that is 4 to 6 times greater than a normal individual. Accordingly, a prolonged period of dialysis may cause topiramate concentration to fall below that required to maintain an anti-seizure effect. To avoid rapid drops in topiramate plasma concentration during hemodialysis, a supplemental dose of topiramate may be required. The actual adjustment should take into account 1) the duration of dialysis period, 2) the clearance rate of the dialysis system being used, and 3) the effective renal clearance of topiramate in the patient being dialyzed.

Patients With Hepatic Disease

In hepatically impaired patients, topiramate plasma concentrations may be increased. The mechanism is not well understood.

HOW SUPPLIED

Dosage Forms And Strengths

TOPAMAX® (topiramate) Tablets are available as debossed, coated, round tablets in the following strengths and colors:

25 mg cream (debossed "OMN" on one side; "25" on the other)

50 mg light-yellow (debossed "OMN" on one side; "50" on the other)

100 mg yellow (debossed "OMN" on one side; "100" on the other)

200 mg salmon (debossed "OMN" on one side; "200" on the other)

TOPAMAX® (topiramate capsules) Sprinkle Capsules contain small, white to off-white spheres. The gelatin capsules are white and clear.

They are marked as follows:

15 mg capsule with "TOP" and "15 mg" on the side

25 mg capsule with "TOP" and "25 mg" on the side

TOPAMAX® Tablets

TOPAMAX® (topiramate) Tablets are available as debossed, coated, round tablets in the following strengths and colors:

25 mg cream tablet (debossed "OMN" on one side; "25" on the other) and are available in bottles of 60 count with desiccant (**NDC** 50458-639-65)

50 mg light yellow tablet (debossed "OMN" on one side; "50" on the other) and are available in bottles of 60 count with desiccant (**NDC** 50458-640-65)

100 mg yellow tablet (debossed "OMN" on one side; "100" on the other) and are available in bottles of 60 count with desiccant (**NDC** 50458-641-65)

200 mg salmon tablet (debossed "OMN" on one side; "200" on the other) and are available in bottles of 60 count with desiccant (**NDC** 50458-642-65)

TOPAMAX® Sprinkle Capsules

TOPAMAX® (topiramate capsules) Sprinkle Capsules contain small, white to off-white spheres. The gelatin capsules are white and clear and are marked as follows:

15 mg capsule with "TOP" and "15 mg" on the side and are available in bottles of 60 (**NDC** 50458-647-65)

25 mg capsule with "TOP" and "25 mg" on the side and are available in bottles of 60 (**NDC** 50458-645-65)

Storage and Handling

TOPAMAX® Tablets should be stored in tightly-closed containers at controlled room temperature (59° to 86°F, 15° to 30°C). Protect from moisture.

TOPAMAX® Sprinkle Capsules should be stored in tightly-closed containers at or below 25°C (77° F). Protect from moisture.

Manufactured by: Janssen Ortho, LLC, Gurabo, Puerto Rico 00778 Manufactured for: Janssen Pharmaceuticals, Inc., Titusville, NJ 08560. Revised January 2014

Last reviewed on RxList: 2/28/2014
This monograph has been modified to include the generic and brand name in many instances.

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SIDE EFFECTS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The following adverse reactions are discussed in more detail in other sections of the labeling:

- Acute Myopia and Secondary Angle Closure [see **WARNINGS AND PRECAUTIONS**]
- Visual Field Defects [see **WARNINGS AND PRECAUTIONS**]
- Oligohidrosis and Hyperthermia [see **WARNINGS AND PRECAUTIONS**]
- Metabolic Acidosis [see **WARNINGS AND PRECAUTIONS**]
- Suicidal Behavior and Ideation [see **WARNINGS AND PRECAUTIONS**]
- Cognitive/Neuropsychiatric Adverse Reactions [see **WARNINGS AND PRECAUTIONS**]
- Fetal Toxicity [see **WARNINGS AND PRECAUTIONS** and **Use in Specific Populations**]
- Withdrawal of Antiepileptic Drugs (AEDs) [see **WARNINGS AND PRECAUTIONS**]
- Sudden Unexplained Death in Epilepsy (SUDEP) [see **WARNINGS AND PRECAUTIONS**]
- Hyperammonemia and Encephalopathy (Without and With Concomitant Valproic Acid [VPA] Use [see **WARNINGS AND PRECAUTIONS**]
- Kidney Stones [see **WARNINGS AND PRECAUTIONS**]
- Hypothermia with Concomitant Valproic Acid (VPA) Use [see **WARNINGS AND PRECAUTIONS**]
- Paresthesia [see **WARNINGS AND PRECAUTIONS**]

The data described in the following sections were obtained using TOPAMAX® (topiramate) Tablets.

Monotherapy Epilepsy

Adults ≥ 16 Years

The adverse reactions in the controlled trial that occurred most commonly in adults in the 400 mg/day TOPAMAX® group and at a rate higher (> 5 %) than in the 50 mg/day group were: paresthesia, weight decrease, anorexia, somnolence, and difficulty with memory (see Table 5).

Approximately 21% of the 159 adult patients in the 400 mg/day group who received topiramate as monotherapy in the controlled clinical trial discontinued therapy due to adverse reactions. The most common (> 2% more frequent than low-dose 50 mg/day TOPAMAX®) adverse reactions causing discontinuation in this trial were difficulty with memory, fatigue, asthenia, insomnia, somnolence, and paresthesia.

Pediatric Patients 6 to < 16 Years of Age

The adverse reactions in the controlled trial that occurred most commonly in pediatric patients in the 400 mg/day TOPAMAX® group and at a rate higher (> 5%) than in the 50 mg/day group were fever, weight decrease, mood problems, cognitive problems, infection, flushing, and paresthesia (see Table 5).

Approximately 14% of the 77 pediatric patients in the 400 mg/day group who received TOPAMAX® as monotherapy in the controlled clinical trial discontinued therapy due to adverse reactions. The most common (> 2% more frequent than low-dose 50 mg/day TOPAMAX®) adverse reactions resulting in discontinuation in this trial were difficulty with concentration/attention, fever, flushing, and confusion.

Table 5: Incidence of Treatment-Emergent Adverse Reactions in Monotherapy Epilepsy Where the Rate Was at Least 2% in Any TOPAMAX® Group and the Rate in the 400 mg/day TOPAMAX® Group Was Greater Than the Rate in the 50 mg/day TOPAMAX® Group for Adults (> 16 Years) and Pediatric (6 to < 16 Years) Patients in Study TOPMAX-EPMN-106

Body System Adverse Reaction	Age Group			
	Pediatric (6 to < 16 Years)		Adult (Age ≥ 16 Years)	
	TOPAMAX® Daily Dosage Group (mg/day)			
	50 (N=74) %*	400 (N=77) %*	50 (N=160) %*	400 (N=159) %*
Body as a Whole - General Disorders				
Asthenia	0	3	4	6
Chest pain			1	2
Fever	1	12		
Leg pain			2	3
Central & Peripheral Nervous System Disorders				
Ataxia			3	4
Dizziness			13	14
Hypertonia			0	3
Hypoesthesia			4	5
Muscle contractions involuntary	0	3		
Paresthesia	3	12	21	40
Vertigo	0	3		
Gastro-Intestinal System Disorders				
Constipation			1	4
Diarrhea	8	9		
Gastritis			0	3
Gastroesophageal reflux			1	2
Dry mouth			1	3
Liver and Biliary System Disorders				
Gamma-GT increased			1	3
Metabolic and Nutritional Disorders				
Weight decrease	7	17	6	17
Platelet, Bleeding & Clotting Disorders				
Epistaxis	0	4		
Psychiatric Disorders				
Anorexia			4	14
Anxiety			4	6
Cognitive problems	1	6	1	4
Confusion	0	3		

Depression	0	3	7	9
Difficulty with concentration/attention	7	10	7	8
Difficulty with memory	1	3	6	11
Insomnia			8	9
Libido decreased			0	3
Mood problems	1	8	2	5
Personality disorder (behavior problems)	0	3		
Psychomotor slowing			3	5
Somnolence			10	15
Red Blood Cell Disorders				
Anemia	1	3		
Reproductive Disorders, Female†				
Intermenstrual Bleeding	0	3		
Vaginal Hemorrhage			0	3
Resistance Mechanism Disorders				
Infection	3	8	2	3
Infection viral	3	6	6	8
Respiratory System Disorders				
Bronchitis	1	5	3	4
Dyspnea			1	2
Rhinitis	5	6	2	4
Sinusitis	1	4		
Upper respiratory tract infection	16	18		
Skin and Appendages Disorders				
Acne			2	3
Alopecia	1	4	3	4
Pruritus			1	4
Rash	3	4	1	4
Special Senses Other, Disorders				
Taste perversion			3	5
Urinary System Disorders				
Cystitis			1	3
Dysuria			0	2
Micturition frequency	0	3	0	2
Renal calculus			0	3
Urinary incontinence	1	3		
Urinary tract infection			1	2
Vascular (Extracardiac) Disorders				
Flushing	0	5		

*Percentages calculated with the number of subjects in each group as denominator

† N with Female Reproductive Disorders – Incidence calculated relative to the number of females; Pediatric TPM 50 mg n=40; Pediatric TPM 400 mg n=33; Adult TPM 50 mg n=84; TPM 400 mg n=80

Adjunctive Therapy Epilepsy

The most commonly observed adverse reactions associated with the use of TOPAMAX® at dosages of 200 to 400 mg/day in controlled trials in adults with partial onset seizures, primary generalized tonic-clonic seizures, or Lennox-Gastaut syndrome, that were seen at greater frequency in TOPAMAX®-treated patients and did not appear to be dose-related were somnolence, dizziness, ataxia, speech disorders and related speech problems, psychomotor

slowing, abnormal vision, difficulty with memory, paresthesia and diplopia (see Table 6). The most common dose-related adverse reactions at dosages of 200 to 1,000 mg/day were fatigue, nervousness, difficulty with concentration or attention, confusion, depression, anorexia, language problems, anxiety, mood problems, and weight decrease (see Table 8).

Adverse reactions associated with the use of TOPAMAX® at dosages of 5 to 9 mg/kg/day in controlled trials in pediatric patients with partial onset seizures, primary generalized tonic-clonic seizures, or Lennox-Gastaut syndrome, that were seen at greater frequency in TOPAMAX®treated patients were fatigue, somnolence, anorexia, nervousness, difficulty with concentration/attention, difficulty with memory, aggressive reaction, and weight decrease (see Table 9).

In controlled clinical trials in adults, 11% of patients receiving TOPAMAX® 200 to 400 mg/day as adjunctive therapy discontinued due to adverse reactions. This rate appeared to increase at dosages above 400 mg/day. Adverse reactions associated with discontinuing therapy included somnolence, dizziness, anxiety, difficulty with concentration or attention, fatigue, and paresthesia and increased at dosages above 400 mg/day. None of the pediatric patients who received TOPAMAX® adjunctive therapy at 5 to 9 mg/kg/day in controlled clinical trials discontinued due to adverse reactions.

Approximately 28% of the 1757 adults with epilepsy who received TOPAMAX® at dosages of 200 to 1,600 mg/day in clinical studies discontinued treatment because of adverse reactions; an individual patient could have reported more than one adverse reaction. These adverse reactions were psychomotor slowing (4.0%), difficulty with memory (3.2%), fatigue (3.2%), confusion (3.1%), somnolence (3.2%), difficulty with concentration/attention (2.9%), anorexia (2.7%), depression (2.6%), dizziness (2.5%), weight decrease (2.5%), nervousness (2.3%), ataxia (2.1%), and paresthesia (2.0%). Approximately 11% of the 310 pediatric patients who received TOPAMAX® at dosages up to 30 mg/kg/day discontinued due to adverse reactions. Adverse reactions associated with discontinuing therapy included aggravated convulsions (2.3%), difficulty with concentration/attention (1.6%), language problems (1.3%), personality disorder (1.3%), and somnolence (1.3%).

Incidence In Epilepsy Controlled Clinical Trials – Adjunctive Therapy – Partial Onset Seizures, Primary Generalized Tonic-Clonic Seizures, And Lennox-Gastaut Syndrome

Table 6 lists treatment-emergent adverse reactions that occurred in at least 1% of adults treated with 200 to 400 mg/day TOPAMAX® in controlled trials that were numerically more common at this dose than in the patients treated with placebo. In general, most patients who experienced adverse reactions during the first eight weeks of these trials no longer experienced them by their last visit. Table 9 lists treatment-emergent adverse reactions that occurred in at least 1% of pediatric patients treated with 5 to 9 mg/kg TOPAMAX® in controlled trials that were numerically more common than in patients treated with placebo.

The prescriber should be aware that these data were obtained when TOPAMAX® was added to concurrent antiepileptic drug therapy and cannot be used to predict the frequency of adverse reactions in the course of usual medical practice where patient characteristics and other factors may differ from those prevailing during clinical studies. Similarly, the cited frequencies cannot be directly compared with data obtained from other clinical investigations involving different treatments, uses, or investigators. Inspection of these frequencies, however, does provide the prescribing physician with a basis to estimate the relative contribution of drug and non-drug factors to the adverse reaction incidences in the population studied.

Other Adverse Reactions Observed During Double-Blind Epilepsy Adjunctive Therapy Trials

Other adverse reactions that occurred in more than 1% of adults treated with 200 to 400 mg of TOPAMAX® in placebo-controlled epilepsy trials but with equal or greater frequency in the placebo group were headache, injury, anxiety, rash, pain, convulsions aggravated, coughing,

fever, diarrhea, vomiting, muscle weakness, insomnia, personality disorder, dysmenorrhea, upper respiratory tract infection, and eye pain.

Table 6: Incidence of Treatment-Emergent Adverse Reactions in Placebo-Controlled, Add-On Epilepsy Trials in Adults[a,b] Where Incidence Was > 1% in Any TOPAMAX® Group and Greater Than the Rate in Placebo-Treated Patients

Body System/ Adverse Reaction[c]	TOPAMAX® Dosage (mg/day)		
	Placebo (N=291)	200-400 (N=183)	600-1,000 (N=414)
Body as a Whole-General Disorders			
Fatigue	13	15	30
Asthenia	1	6	3
Back pain	4	5	3
Chest pain	3	4	2
Influenza-like symptoms	2	3	4
Leg pain	2	2	4
Hot flushes	1	2	1
Allergy	1	2	3
Edema	1	2	1
Body odor	0	1	0
Rigors	0	1	< 1
Central & Peripheral Nervous System Disorders			
Dizziness	15	25	32
Ataxia	7	16	14
Speech disorders/Related speech problems	2	13	11
Paresthesia	4	11	19
Nystagmus	7	10	11
Tremor	6	9	9
Language problems	1	6	10
Coordination abnormal	2	4	4
Hypoesthesia	1	2	1
Gait abnormal	1	3	2
Muscle contractions involuntary	1	2	2
Stupor	0	2	1
Vertigo	1	1	2
Gastro-Intestinal System Disorders			
Nausea	8	10	12
Dyspepsia	6	7	6
Abdominal pain	4	6	7
Constipation	2	4	3
Gastroenteritis	1	2	1
Dry mouth	1	2	4
Gingivitis	< 1	1	1
GI disorder	< 1	1	0
Hearing and Vestibular Disorders			
Hearing decreased	1	2	1
Metabolic and Nutritional Disorders			
Weight decrease	3	9	13
Muscle-Skeletal System Disorders			
Myalgia	1	2	2
Skeletal pain	0	1	0
Platelet, Bleeding, & Clotting Disorders			

Epistaxis	1	2	1
Psychiatric Disorders			
Somnolence	12	29	28
Nervousness	6	16	19
Psychomotor slowing	2	13	21
Difficulty with memory	3	12	14
Anorexia	4	10	12
Confusion	5	11	14
Depression	5	5	13
Difficulty with concentration/attention	2	6	14
Mood problems	2	4	9
Agitation	2	3	3
Aggressive reaction	2	3	3
Emotional lability	1	3	3
Cognitive problems	1	3	3
Libido decreased	1	2	< 1
Apathy	1	1	3
Depersonalization	1	1	2
Reproductive Disorders, Female			
Breast pain	2	4	0
Amenorrhea	1	2	2
Menorrhagia	0	2	1
Menstrual disorder	1	2	1
Reproductive Disorders, Male			
Prostatic disorder	< 1	2	0
Resistance Mechanism Disorders			
Infection	1	2	1
Infection viral	1	2	< 1
Moniliasis	< 1	1	0
Respiratory System Disorders			
Pharyngitis	2	6	3
Rhinitis	6	7	6
Sinusitis	4	5	6
Dyspnea	1	1	2
Skin and Appendages Disorders			
Skin disorder	< 1	2	1
Sweating increased	< 1	1	< 1
Rash erythematous	< 1	1	< 1
Special Sense Other, Disorders			
Taste perversion	0	2	4
Urinary System Disorders			
Hematuria	1	2	< 1
Urinary tract infection	1	2	3
Micturition frequency	1	1	2
Urinary incontinence	< 1	2	1
Urine abnormal	0	1	< 1
Vision Disorders			
Vision abnormal	2	13	10
Diplopia	5	10	10
White Cell and RES Disorders			
Leukopenia	1	2	1

[a] Patients in these add-on/ adjunctive trials were receiving 1 to 2 concomitant antiepileptic drugs in addition to TOPAMAX® or placebo.
[b] Values represent the percentage of patients reporting a given adverse reaction. Patients may have reported more than one adverse reaction during the study and can be included in more than one adverse reaction category.
[c] Adverse reactions reported by at least 1% of patients in the TOPAMAX® 200-400 mg/day group and more common than in the placebo group are listed in this table.

Incidence In Study 119 – Add-On Therapy– Adults With Partial Onset Seizures

Study 119 was a randomized, double-blind, add-on/adjunctive, placebo-controlled, parallel group study with 3 treatment arms: 1) placebo; 2) TOPAMAX® 200 mg/day with a 25 mg/day starting dose, increased by 25 mg/day each week for 8 weeks until the 200 mg/day maintenance dose was reached; and 3) TOPAMAX® 200 mg/day with a 50 mg/day starting dose, increased by 50 mg/day each week for 4 weeks until the 200 mg/day maintenance dose was reached. All patients were maintained on concomitant carbamazepine with or without another concomitant antiepileptic drug.

The incidence of adverse reactions (Table 7) did not differ significantly between the 2 TOPAMAX® regimens. Because the frequencies of adverse reactions reported in this study were markedly lower than those reported in the previous epilepsy studies, they cannot be directly compared with data obtained in other studies.

Table 7: Incidence of Treatment-Emergent Adverse Reactions in Study 119[a,b] Where Incidence Was > 2% in the TOPAMAX® Group and Greater Than the Rate in Placebo-Treated Patients

Body System/ Adverse Reactionc	TOPAMAX® Dosage (mg/day)	
	Placebo (N=92)	200 (N=171)
Body as a Whole-General Disorders		
Fatigue	4	9
Chest pain	1	2
Cardiovascular Disorders, General		
Hypertension	0	2
Central & Peripheral Nervous System Disorders		
Paresthesia	2	9
Dizziness	4	7
Tremor	2	3
Hypoesthesia	0	2
Leg cramps	0	2
Language problems	0	2
Gastro-Intestinal System Disorders		
Abdominal pain	3	5
Constipation	0	4
Diarrhea	1	2
Dyspepsia	0	2
Dry mouth	0	2
Hearing and Vestibular Disorders		
Tinnitus	0	2
Metabolic and Nutritional Disorders		
Weight decrease	4	8

Psychiatric Disorders		
Somnolence	9	15
Anorexia	7	9
Nervousness	2	9
Difficulty with concentration/attention	0	5
Insomnia	3	4
Difficulty with memory	1	2
Aggressive reaction	0	2
Respiratory System Disorders		
Rhinitis	0	4
Urinary System Disorders		
Cystitis	0	2
Vision Disorders		
Diplopia	0	2
Vision abnormal	0	2

[a]Patients in these add-on/adjunctive trials were receiving 1 to 2 concomitant antiepileptic drugs in addition to TOPAMAX® or placebo.

[b]Values represent the percentage of patients reporting a given adverse reaction. Patients may have reported more than one adverse reaction during the study and can be included in more than one adverse reaction category.

[c] Adverse reactions reported by at least 2% of patients in the TOPAMAX® 200 mg/day group and more common than in the placebo group are listed in this table.

Table 8: Incidence (%) of Dose-Related Adverse Reactions From Placebo-Controlled, Add-On Trials in Adults With Partial Onset Seizuresa

Adverse Reaction	Placebo (N = 216)	TOPAMAX® Dosage(mg/day) 200 (N = 45)	400 (N = 68)	600 - 1,000 (N = 414)
Fatigue	13	11	12	30
Nervousness	7	13	18	19
Difficulty with concentration/attention	1	7	9	14
Confusion	4	9	10	14
Depression	6	9	7	13
Anorexia	4	4	6	12
Language problems	< 1	2	9	10
Anxiety	6	2	3	10
Mood problems	2	0	6	9
Weight decrease	3	4	9	13

[a]Dose-response studies were not conducted for other adult indications or for pediatric indications.

Table 9: Incidence (%) of Treatment-Emergent Adverse Reactions in Placebo-Controlled, Add-On Epilepsy Trials in Pediatric Patients (Ages 2 -16 Years)[a,b] (Reactions That Occurred in at Least 1% of TOPAMAX®Treated Patients and Occurred More Frequently in TOPAMAX®Treated Than Placebo-Treated Patients)

Body System/ Adverse Reaction	Placebo (N=101)	TOPAMAX® (N=98)
Body as a Whole - General Disorders		
Fatigue	5	16
Injury	13	14

Allergic reaction	1	2
Back pain	0	1
Pallor	0	1
Cardiovascular Disorders, General		
Hypertension	0	1
Central & Peripheral Nervous System Disorders		
Gait abnormal	5	8
Ataxia	2	6
Hyperkinesia	4	5
Dizziness	2	4
Speech disorders/Related speech problems	2	4
Hyporeflexia	0	2
Convulsions grand mal	0	1
Fecal incontinence	0	1
Paresthesia	0	1
Gastro-Intestinal System Disorders		
Nausea	5	6
Saliva increased	4	6
Constipation	4	5
Gastroenteritis	2	3
Dysphagia	0	1
Flatulence	0	1
Gastroesophageal reflux	0	1
Glossitis	0	1
Gum hyperplasia	0	1
Bradycardia	0	1
Metabolic and Nutritional Disorders		
Weight decrease	1	9
Thirst	1	2
Hypoglycemia	0	1
Weight increase	0	1
Platelet, Bleeding, & Clotting Disorders		
Purpura	4	8
Epistaxis	1	4
Hematoma	0	1
Prothrombin increased	0	1
Thrombocytopenia	0	1
Psychiatric Disorders		
Somnolence	16	26
Anorexia	15	24
Nervousness	7	14
Personality disorder (behavior problems)	9	11
Difficulty with concentration/attention	2	10
Aggressive reaction	4	9
Insomnia	7	8
Difficulty with memory	0	5
Confusion	3	4
Psychomotor slowing	2	3
Appetite increased	0	1
Neurosis	0	1
Reproductive Disorders, Female		
Leukorrhea	0	2
Resistance Mechanism Disorders		
Infection viral	3	7

Respiratory System Disorders		
Pneumonia	1	5
Respiratory disorder	0	1
Skin and Appendages Disorders		
Skin disorder	2	3
Alopecia	1	2
Dermatitis	0	2
Hypertrichosis	1	2
Rash erythematous	0	2
Eczema	0	1
Seborrhea	0	1
Skin discoloration	0	1
Urinary System Disorders		
Urinary incontinence	2	4
Nocturia	0	1
Vision Disorders		
Eye abnormality	1	2
Vision abnormal	1	2
Diplopia	0	1
Lacrimation abnormal	0	1
Myopia White Cell and RES Disorders	0	1
Leukopenia	0	2

[a]Patients in these add-on/adjunctive trials were receiving 1 to 2 concomitant antiepileptic drugs in addition to TOPAMAX® or placebo.
[b]Values represent the percentage of patients reporting a given adverse reaction. Patients may have reported more than one adverse reaction during the study and can be included in more than one adverse reaction category.

Other Adverse Reactions Observed During All Epilepsy Clinical Trials

TOPAMAX® has been administered to 2246 adults and 427 pediatric patients with epilepsy during all clinical studies, only some of which were placebo-controlled. During these studies, all adverse reactions were recorded by the clinical investigators using terminology of their own choosing. To provide a meaningful estimate of the proportion of individuals having adverse reactions, similar types of reactions were grouped into a smaller number of standardized categories using modified WHOART dictionary terminology. The frequencies presented represent the proportion of patients who experienced a reaction of the type cited on at least one occasion while receiving TOPAMAX®. Reported reactions are included except those already listed in the previous tables or text, those too general to be informative, and those not reasonably associated with the use of the drug.

Reactions are classified within body system categories and enumerated in order of decreasing frequency using the following definitions: *frequent* occurring in at least 1/100 patients; *infrequent* occurring in 1/100 to 1/1000 patients; *rare* occurring in fewer than 1/1000 patients.

Autonomic Nervous System Disorders: *Infrequent*: vasodilation.

Body as a Whole: *Frequent*: syncope. *Infrequent*: abdomen enlarged. *Rare*: alcohol intolerance.

Cardiovascular Disorders, General: *Infrequent*: hypotension, postural hypotension, angina pectoris.

Central & Peripheral Nervous System Disorders: *Infrequent*: neuropathy, apraxia, hyperesthesia, dyskinesia, dysphonia, scotoma, ptosis, dystonia, visual field defect[1], encephalopathy, EEG abnormal. *Rare*: upper motor neuron lesion, cerebellar syndrome, tongue paralysis.

Gastrointestinal System Disorders: *Infrequent*: hemorrhoids, stomatitis, melena, gastritis, esophagitis. *Rare*: tongue edema.

Heart Rate and Rhythm Disorders: *Infrequent*: AV block.

Liver and Biliary System Disorders: *Infrequent*: SGPT increased, SGOT increased.

Metabolic and Nutritional Disorders: *Infrequent*: dehydration, hypocalcemia, hyperlipemia, hyperglycemia, xerophthalmia, diabetes mellitus. *Rare*: hypernatremia, hyponatremia, hypocholesterolemia, creatinine increased.

Musculoskeletal System Disorders: *Frequent*: arthralgia. *Infrequent*: arthrosis.

Neoplasms: *Infrequent*: thrombocythemia. *Rare*: polycythemia.

Platelet, Bleeding, and Clotting Disorders: *Infrequent*: gingival bleeding, pulmonary embolism.

Psychiatric Disorders: *Frequent*: impotence, hallucination, psychosis, suicide attempt. Infrequent: euphoria, paranoid reaction, delusion, paranoia, delirium, abnormal dreaming. *Rare*: libido increased, manic reaction.

Red Blood Cell Disorders: *Frequent*: anemia. *Rare*: marrow depression, pancytopenia.

Reproductive Disorders, Male: *Infrequent*: ejaculation disorder, breast discharge.

Skin and Appendages Disorders: *Infrequent*: urticaria, photosensitivity reaction, abnormal hair texture. *Rare*: chloasma.

Special Senses Other, Disorders: *Infrequent*: taste loss, parosmia.

Urinary System Disorders: *Infrequent*: urinary retention, face edema, renal pain, albuminuria, polyuria, oliguria.

Vascular (Extracardiac) Disorders: *Infrequent*: flushing, deep vein thrombosis, phlebitis. *Rare*: vasospasm.

Vision Disorders: *Frequent*: conjunctivitis. *Infrequent*: abnormal accommodation, photophobia, strabismus. *Rare*: mydriasis, iritis.

White Cell and Reticuloendothelial System Disorders: *Infrequent*: lymphadenopathy, eosinophilia, lymphopenia, granulocytopenia. *Rare*: lymphocytosis.

Migraine

In the four multicenter, randomized, double-blind, placebo-controlled, parallel group migraine prophylaxis clinical trials, most of the adverse reactions with TOPAMAX® were mild or moderate in severity. Most adverse reactions occurred more frequently during the titration period than during the maintenance period.

Table 10 includes those adverse reactions reported for patients in the placebo-controlled trials where the incidence in any TOPAMAX® treatment group was at least 2% and was greater than that for placebo patients.

Table 10: Incidence of Treatment-Emergent Adverse Reactions in Placebo-Controlled, Migraine Trials Where Incidence Was > 2 % in Any TOPAMAX® Group and Greater Than the Rate in Placebo-Treated Patients [a]

Body System/ Adverse Reaction	Placebo (N=445)	TOPAMAX® Dosage (mg/day) 50 (N=235)	100 (N=386)	200 (N=514)
Body as a Whole-General Disorders				

Fatigue	11	14	15	19
Injury	7	9	6	6
Asthenia	1	< 1	2	2
Fever	1	1	1	2
Influenza-like symptoms	< 1	< 1	< 1	2
Allergy	< 1	2	< 1	< 1
Central & Peripheral Nervous System Disorders				
Paresthesia	6	35	51	49
Dizziness	10	8	9	12
Hypoesthesia	2	6	7	8
Language problems	2	7	6	7
Involuntary muscle contractions	1	2	2	4
Ataxia	< 1	1	2	1
Speech disorders/Related speech problems	< 1	1	< 1	2
Gastro-Intestinal System Disorders				
Nausea	8	9	13	14
Diarrhea	4	9	11	11
Abdominal pain	5	6	6	7
Dyspepsia	3	4	5	3
Dry mouth	2	2	3	5
Vomiting	2	1	2	3
Gastroenteritis	1	3	3	2
Hearing and Vestibular Disorders				
Tinnitus	1	< 1	1	2
Metabolic and Nutritional Disorders				
Weight decrease	1	6	9	11
Thirst	< 1	2	2	1
Musculoskeletal System Disorders				
Arthralgia	2	7	3	1
Neoplasms				
Neoplasm	< 1	2	< 1	< 1
Psychiatric Disorders				
Anorexia	6	9	15	14
Somnolence	5	8	7	10
Difficulty with memory	2	7	7	11
Difficulty with concentration/ attention	2	3	6	10
Insomnia	5	6	7	6
Anxiety	3	4	5	6
Mood problems	2	3	6	5
Depression	4	3	4	6
Nervousness	2	4	4	4
Confusion	2	2	3	4
Psychomotor slowing	1	3	2	4
Libido decreased	1	1	1	2
Aggravated depression	1	1	2	2
Agitation	1	2	2	1
Cognitive problems	1	< 1	2	2
Reproductive Disorders, Female				
Menstrual disorder	2	3	2	2
Reproductive Disorders, Male				
Ejaculation premature	0	3	0	0

Resistance Mechanism Disorders				
Viral infection	3	4	4	3
Otitis media	< 1	2	1	1
Respiratory System Disorders				
Upper respiratory tract infection	12	13	14	12
Sinusitis	6	10	6	8
Pharyngitis	4	5	6	2
Coughing	2	2	4	3
Bronchitis	2	3	3	3
Dyspnea	2	1	3	2
Rhinitis	1	1	2	2
Skin and Appendages Disorders				
Pruritis	2	4	2	2
Special Sense Other, Disorders				
Taste perversion	1	15	8	12
Taste loss	< 1	1	1	2
Urinary System Disorders				
Urinary tract infection	2	4	2	4
Renal calculus	0	0	1	2
Vision Disorders				
Vision abnormal	< 1	1	2	3
Blurred vision [b]	2	4	2	4
Conjunctivitis	1	1	2	1

[a]Values represent the percentage of patients reporting a given adverse reaction. Patients may have reported more than one adverse reaction during the study and can be included in more than one adverse reaction category.

[b]Blurred vision was the most common term considered as vision abnormal. Blurred vision was an included term that accounted for > 50% of reactions coded as vision abnormal, a preferred term.

Of the 1135 patients exposed to TOPAMAX® in the placebo-controlled studies, 25% discontinued due to adverse reactions, compared to 10% of the 445 placebo patients. The adverse reactions associated with discontinuing therapy in the TOPAMAX® -treated patients included paresthesia (7%), fatigue (4%), nausea (4%), difficulty with concentration/attention (3%), insomnia (3%), anorexia (2%), and dizziness (2%).

Patients treated with TOPAMAX® experienced mean percent reductions in body weight that were dose-dependent. This change was not seen in the placebo group. Mean changes of 0%, -2%, -3%, and -4% were seen for the placebo group, TOPAMAX® 50, 100, and 200 mg groups, respectively.

Table 11 shows adverse reactions that were dose-dependent. Several central nervous system adverse reactions, including some that represented cognitive dysfunction, were dose-related. The most common dose-related adverse reactions were paresthesia, fatigue, nausea, anorexia, dizziness, difficulty with memory, diarrhea, weight decrease, difficulty with concentration/attention, and somnolence.

Table 11: Incidence (%) of Dose-Related Adverse Reactions From Placebo-Controlled, Migraine Trials[a]

Adverse Reaction	Placebo (N=445)	TOPAMAX® Dosage (mg/day) 50 (N=235)	100 (N=386)	200 (N=514)
Paresthesia	6	35	51	49
Fatigue	11	14	15	19

Nausea	8	9	13	14
Anorexia	6	9	15	14
Dizziness	10	8	9	12
Weight decrease	1	6	9	11
Difficulty with memory	2	7	7	11
Diarrhea	4	9	11	11
Difficulty with concentration/ attention	2	3	6	10
Somnolence	5	8	7	10
Hypoesthesia	2	6	7	8
Anxiety	3	4	5	6
Depression	4	3	4	6
Mood problems	2	3	6	5
Dry mouth	2	2	3	5
Confusion	2	2	3	4
Involuntary muscle contractions	1	2	2	4
Abnormal vision	< 1	1	2	3
Renal calculus	0	0	1	2

[a]The incidence of adverse reactions in the 200 mg/day group was > 2% than the incidence in both the placebo group and the 50 mg/day group.

Other Adverse Reactions Observed During Migraine Clinical Trials

TOPAMAX®, for the treatment of prophylaxis of migraine headache, has been administered to 1367 patients in all clinical studies (includes double-blind and open-label extension). During these studies, all adverse reactions were recorded by the clinical investigators using terminology of their own choosing. To provide a meaningful estimate of the proportion of individuals having adverse reactions, similar types of reactions were grouped into a smaller number of standardized categories using modified WHOART dictionary terminology.

The following additional adverse reactions that were not described earlier were reported by greater than 1% of the 1367 TOPAMAX®-treated patients in the controlled clinical trials:

Body as a Whole: Pain, chest pain, allergic reaction.

Central & Peripheral Nervous System Disorders: Headache, vertigo, tremor, sensory disturbance, migraine aggravated.

Gastrointestinal System Disorders: Constipation, gastroesophageal reflux.

Musculoskeletal System Disorders: Myalgia.

Platelet, Bleeding, and Clotting Disorders: Epistaxis.

Reproductive Disorders, Female: Intermenstrual bleeding.

Resistance Mechanism Disorders: Infection, genital moniliasis.

Respiratory System Disorders: Pneumonia, asthma.

Skin and Appendages Disorders: Rash, alopecia.

Vision Disorders: Abnormal accommodation, eye pain.

Postmarketing And Other Experience

In addition to the adverse experiences reported during clinical testing of TOPAMAX®, the following adverse experiences have been reported worldwide in patients receiving TOPAMAX® post-approval.

These adverse experiences have not been listed above and data are insufficient to support an estimate of their incidence or to establish causation. The listing is alphabetized: bullous skin reactions (including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis), hepatic failure (including fatalities), hepatitis, maculopathy, pancreatitis, and pemphigus.

Read the Topamax (topiramate) Side Effects Center for a complete guide to possible side effects

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DRUG INTERACTIONS

In vitro studies indicate that topiramate does not inhibit enzyme activity for CYP1A2, CYP2A6, CYP2B6, CYP2C9, CYP2D6, CYP2E1, and CYP3A4/5 isozymes. In vitro studies indicate that topiramate is a mild inhibitor of CYP2C19 and a mild inducer of CYP3A4. Drug interactions with some antiepileptic drugs, CNS depressants and oral contraceptives are described here. For other drug interactions, please refer to Clinical Pharmacology.

Antiepileptic Drugs

Potential interactions between topiramate and standard AEDs were assessed in controlled clinical pharmacokinetic studies in patients with epilepsy. Concomitant administration of phenytoin or carbamazepine with topiramate decreased plasma concentrations of topiramate by 48% and 40%, respectively when compared to TOPAMAX® given alone [see **CLINICAL PHARMACOLOGY**]

Concomitant administration of valproic acid and TOPAMAX® has been associated with hyperammonemia with and without encephalopathy. Concomitant administration of TOPAMAX® with valproic acid has also been associated with hypothermia (with and without hyperammonemia) in patients who have tolerated either drug alone. It may be prudent to examine blood ammonia levels in patients in whom the onset of hypothermia has been reported [see **WARNINGS AND PRECAUTIONS** or CLINICAL PHARMACOLOGY].

CNS Depressants

Concomitant administration of TOPAMAX® and alcohol or other CNS depressant drugs has not been evaluated in clinical studies. Because of the potential of topiramate to cause CNS depression, as well as other cognitive and/or neuropsychiatric adverse reactions, TOPAMAX® should be used with extreme caution if used in combination with alcohol and other CNS depressants.

Oral Contraceptives

Exposure to ethinyl estradiol was statistically significantly decreased at doses of 200, 400, and 800 mg/day (18%, 21%, and 30%, respectively) when TOPAMAX® was given as adjunctive therapy in patients taking valproic acid. However, norethindrone exposure was not significantly affected. In another pharmacokinetic interaction study in healthy volunteers with a concomitantly administered combination oral contraceptive product containing 1 mg norethindrone (NET) plus 35 mcg ethinyl estradiol (EE), TOPAMAX® , given in the absence of other medications at doses of 50 to 200 mg/day, was not associated with statistically significant changes in mean exposure (AUC) to either component of the oral contraceptive. The possibility of decreased contraceptive efficacy and increased breakthrough bleeding should be considered in patients taking combination oral contraceptive products with TOPAMAX®. Patients taking estrogen-containing contraceptives

should be asked to report any change in their bleeding patterns. Contraceptive efficacy can be decreased even in the absence of breakthrough bleeding [see CLINICAL PHARMACOLOGY].

Metformin

Topiramate treatment can frequently cause metabolic acidosis, a condition for which the use of metformin is contraindicated [see **CLINICAL PHARMACOLOGY**].

Lithium

In patients, lithium levels were unaffected during treatment with topiramate at doses of 200 mg/day; however, there was an observed increase in systemic exposure of lithium (27% for Cmax and 26% for AUC) following topiramate doses of up to 600 mg/day. Lithium levels should be monitored when co-administered with high-dose TOPAMAX® [see **CLINICAL PHARMACOLOGY**].

Other Carbonic Anhydrase Inhibitors

Concomitant use of topiramate, a carbonic anhydrase inhibitor, with any other carbonic anhydrase inhibitor (e.g., zonisamide, acetazolamide, or dichlorphenamide) may increase the severity of metabolic acidosis and may also increase the risk of kidney stone formation. Therefore, if TOPAMAX® is given concomitantly with another carbonic anhydrase inhibitor, the patient should be monitored for the appearance or worsening of metabolic acidosis [see CLINICAL PHARMACOLOGY].

Drug Abuse And Dependence

Controlled Substance

TOPAMAX® (topiramate) is not a controlled substance.

Abuse

The abuse and dependence potential of TOPAMAX® has not been evaluated in human studies.

Dependence

TOPAMAX® has not been systematically studied in animals or humans for its potential for tolerance or physical dependence.

Read the Topamax Drug Interactions Center for a complete guide to possible interactions

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Last reviewed on RxList: 2/28/2014
This monograph has been modified to include the generic and brand name in many instances.
