Safety Data Sheet
Topiramate Tablets USP

Strength: 25, 50, 100, 200 mg. **Pack Size:** **Pack Size:** 60,90,100,500 Tablets per bottle **Revision No.:** 02

EMERGENCY OVERVIEW

Each Topiramate Tablets USP intended for oral administration contains Topiramate and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

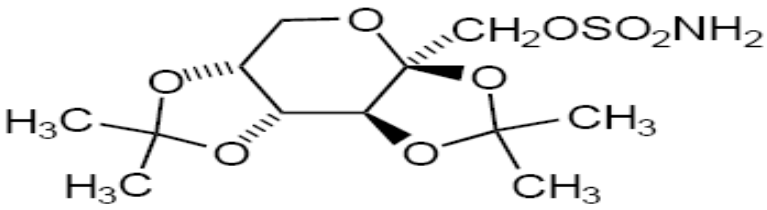
Section 1. Identification

Identification of the product

Product name: Topiramate Tablets USP

Chemical Formula: $C_{12}H_{21}NO_8S$

Chemical Name: 2,3:4, 5-Di-O-isopropylidene-β-D-fructopyranose sulfamate



Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd. Ahmedabad, India**
Address:	Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand. Dist. Ahmedabad – 382210. State: Gujarat. India
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency Telephone No.	Tel.: +91 79 6868100
Recommended use / Therapeutic Category	Topiramate is a sulfamate-substitude monosaccharide having anticonvulsant effects.
. **Restriction on Use / Contraindications**	Topiramate tablets are contraindicated in patients with a history of hypersensitivity to any component of this product.

Section 2. Hazard(s) Information

Dose and Administration

The recommended dose for Topiramate monotherapy in adults and children 10 years of age and older is 400 mg/day in two divided doses. The recommended total daily dose of Topiramate tablets as adjunctive therapy in adults with partial seizures is 200-400 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.

Adverse Effects

Body as a Whole-General Disorders
Asthenia, Leg Pain, Chest Pain
Central & Peripheral Nervous System Disorders
Paresthesia, Dizziness, Hypoaesthesia, Ataxia, Hypertonia
Gastro-Intestinal System Disorders
Diarrhea, Constipation, Gastritis, Dry Mouth, Gastroesophageal Reflux
Liver and Biliary System Disorders
Gamma-GT Increased
Metabolic and Nutritional Disorders
Weight Decreased
Psychiatric Disorders
Somnolence, Anorexia, Difficulty with Memory NOS, Insomnia, Depression, Difficulty with Concentration/Attention, Anxiety, Psychomotor Slowing, Mood Problems, Confusion, Cognitive Problem NOS, Libido Decreased.
Red Blood Cell Disorders
Anemia
Resistance Mechanism Disorders
Infection Viral Infection
Respiratory System Disorders
Bronchitis, Rhinitis, Dyspnea
Skin and Appendages Disorders
Rash, Pruritis, Acne
Special Senses Other, Disorders
Taste Perversion
Urinary System Disorders
Cystitis, Renal Calculus , Urinary Tract Infection, Dysuria, Micturition Frequency
Reproductive Disorders, Female
Vaginal Hemorrhage

Over Dose Effect

Overdoses of topiramate tablets have been reported. Signs and symptoms included convulsions, drowsiness, speech disturbance, blurred vision, diplopia, mentation impaired, lethargy, abnormal coordination, stupor, hypotension, abdominal pain,

agitation, dizziness and depression.

Contraindications

Topiramate tablets are contraindicated in patients with a history of hypersensitivity to any component of this product.

Medical Condition

- Acute myopia and secondary angle closure glaucoma: Untreated elevated intraocular pressure can lead to permanent visual loss. The primary treatment to reverse symptoms is discontinuation of topiramte as rapidly as possible.
- Visual field defects: These have been reported independent of elevated intraocular pressure. Consider discontinuation of topiramate.
- Oligohidrosis and hyperthermia: Monitor decreased sweating and increased body temperature, especially in pediatric patients.
- Metabolic acidosis: Baseline and periodic measurement of serum bicarbonate is recommended. Consider dose reduction or discontinuation of topiramte if clinically appropriate.
- Suicidal behavior and ideation: Antiepileptic drugs increase the risk of suicidal behavior or ideation.
- Cognitive/neuropsychiatric: Topiramte may cause cognitive dysfunction. Patients should use caution when operating machinery including automobiles. Depression and mood problems may occur in epilepsy.
- Fetal Toxicity: Topiramate use during pregnancy can cause cleft lip and/or palate.
- Withdrawal of AEDs: Withdrawal of topiramte should be done gradually.
- Hyperammonemia and encephalopathy associated with or without concomitant valproic acid use: Patients with inborn errors of metabolism or reduced mitochondrial activity may have an increased risk of hyperammonemia. Measure ammonia if encephalopathic symptoms occur.
- Kidney stones: Use with other carbonic anhydrase inhibitors, other drugs causing metabolic acidosis, or in patients on a ketogenic diet should be avoided.
- Hypothermia has been reported with and without hyperammonemia during topiramate treatment with concomitant valproic acid use.

Pregnancy Comments

Topiramate has demonstrated selective developmental toxicity, including teratogenicity, in experimental animal studies.

Pregnancy Category **C**

Section 3. Composition / information on ingredient

Component	Exposure Limit	CAS No.
Principle Component :		
Topiramate	Not Found	97240-79-4
Inactive Ingredients:		
Colloidal silicon dioxide	Not Found	7621-86-9
Hypromellose,	Not Found	9004-65-3
Lactose anhydrous,	Not Found	64044-51-5
Magnesium stearate,	Not Found	557-04-0
Microcrystalline cellulose,	Not Found	9004-34-6
Polyethylene glycol,	Not Found	25322-68-3
Sodium starch glycolate,	Not Found	9063-38-1
Talc	Not Found	14807-96-6
Titanium dioxide.	Not Found	13463-67-7

Section 4. First - aid measures

General Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention.

Overdose Treatment In acute topiramate tablets overdose, if the ingestion is recent, the stomach should be emptied immediately by lavage or by induction of emesis. Activated charcoal has been shown to adsorb topiramate in vitro. Treatment should be appropriately supportive. Hemodialysis is an effective means of removing topiramate from the body.

Section 5. Fire - fighting measures

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable Limit:**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	This material is assumed to be combustible. As with all dry powders it is advisable to ground

	mechanical equipment in contact with the dry material to dissipate the potential build-up of static electricity.
Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Spill Response	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage	Store at 20^{o} to 25^{o} C (68^{o} to 77^{o} F) [See USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container.
Incompatibilities:	No data available.

Section 8. Exposure controls / personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Engineering Control	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9. Physical and chemical properties

Appearance

Topiramate Tablets, 25 mg are white to off-white, round-shaped, biconvex, beveled- edge,film-coated tablets debossed with "ZD 16" on one side and plain on the other side .

Topiramate Tablets, 50 mg are white to off-white, round-shaped, biconvex, beveled- edge, film-coated tablets debossed with "ZD 15" on one side and plain on the other side.

Topiramate Tablets, 100 mg are white to off-white, round-shaped, biconvex, beveled- edge, film-coated tablets debossed with "ZD 14" on one side and plain on the other side.

Topiramate Tablets, 200 mg are white to off-white, round-shaped, biconvex, beveled- edge, film-coated tablets debossed with "ZD 13" on one side and plain on the other side .

Solubility in water	No Data Available	**Odour**	Odourless
Boiling point	No Data Available	**Melting Point**	No Data Available
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
% Volatile by volume	No Data Available	**Specific gravity**	No Data Available
		Vapour pressure	No Data Available

Other information Topiramate, USP is a white to off-white crystalline powder with bitter taste. It is freely soluble in dichloromethane. Topiramate has the molecular formula $C_{12}H_{21}NO_8S$ and a molecular weight of 339.36. Topiramate is designated chemically as 2,3:4,5-Di-O-isopropylidene-β-D-fructopyranose sulfamate

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.
Incompatibilities:	No Data available.		

Section 11. Toxicological information

General Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is Tablets.
Other	No data available

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 078235

Section 16. Other information

None

Date of issue: 28/05/2015 **Supersedes edition of:** 01

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.