Safety Data Sheet
Topiramate Capsules

Strength: 15mg and 25 mg. **Pack Size:** 60,90,100,500 and 1000 Capsules per bottle
Pack Size: 28,60,90,100,500 and 1000 Capsules per bottle **Revision No.:** 02

EMERGENCY OVERVIEW

Each Topiramate Capsules 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.

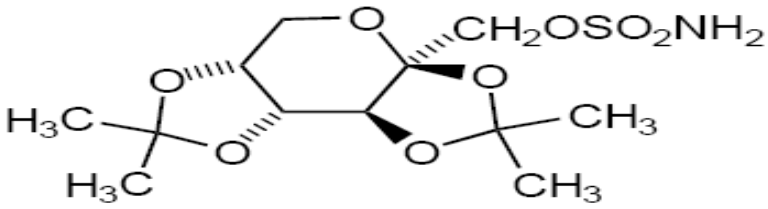
Section 1. Identification

Identification of the product

Product name: Topiramate Capsules

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

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Recommended use / Therapeutic Category **A**nticonvulsant.

. **Restriction on Use / Contraindications** Topiramate capsules 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 capsules as adjunctive therapy in adults with partial seizures is 200-400 mg/day in two divided doses.

Adverse Effects

Adverse events most often associated with the use of topiramate capsules were related to the central nervous system and were observed in the epilepsy populations. In adults, the most frequent of these can be classified into three general categories;1) Cognitive-related dysfunction (e.g. confusion, psychomotor slowing, difficulty with concentration/attention, difficulty with memory, speech or language problems, particularly word-finding difficulties); 2) Psychiatric/behavioral disturbances (e.g. depression or mood problems); and 3) Somnolence or fatigue.

Over Dose Effect

Overdoses of topiramate capsules 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. The clinical consequences were not severe in most cases, but deaths have been reported after poly-drug overdoses involving topiramate capsules. Topiramate overdose has resulted in severe metabolic acidosis

Contraindications

Topiramate Capsuless 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. When oral doses of 20, 100, or 500 mg/kg were administered to pregnant mice during the period of organogenesis, the incidence of fetal malformations (primarily craniofacial defects) was increased at all doses.

Pregnancy Category **C**

Section 3. Composition / information on ingredient

Component	Exposure Limit	CAS No.
Principle Component :		
Topiramate	Not Found	104-31-4
Inactive Ingredients :		
Cellulose acetate	Not Found	9004-35-7
Gelatin	Not Found	9000-70-8
Hydroxypropyl methylcellulose	Not Found	9050-31-1
Povidone	Not Found	9003-39-8
Sodium lauryl sulfate	Not Found	151-21-3
Sugar spheres	Not Found	5989-81-1
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 Capsules 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). Protect from moisture.

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 Capsules, 15 mg are white to off-white pellets filled in size '2' empty hard gelatin capsules with white opaque cap imprinted with "ZA63" and white opaque body imprinted with "15 mg" in black ink.

Topiramate Capsules, 25 mg are white to off-white pellets filled in size '1' empty hard gelatin capsules with white opaque cap imprinted with "ZA64" and white opaque body imprinted with "25 mg" in black ink.

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 C12H21NO8S 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 capsules.

Other Rare instances of deliberate or accidental overdose have resulted in death.

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 78-877

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.