Material Safety Data Sheet

Topiramate Tablets

Strength: 25, 50,100,200mg. **Pack Size:** 60,90,100,500 Tablets per bottle **Revision No.:** 00

EMERGENCY OVERVIEW

TOPIRAMATE TABLETS contain 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 of the substance

Identification of the product

Product name:	TOPIRAMATE TABLETS
Chemical Formula:	$C_{12}H_{21}NO_8S$
Chemical Name:	2,3:4,5-Di-*O*-isopropylidene-β-D-fructopyranose sulfamate
Therapeutic Category	Topiramate is a sulfamate-substituted monosaccharide having anticonvulsant effects.

Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd. Ahmedabad, India**
Contact for information:	Tel.: +91 2717 250337 Fax: +91 2717 250319
Emergency telephone No.	Tel.: +91 2717 250331, 250332, 250336

Section 2. Composition / information on ingredients

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 3. Health Hazards 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.

Pregnancy Comments

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

Pregnancy Category

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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. Storage / Spill / Disposal Measures

Storage Store at 20°-25°C (68°-77°F)
Dispense in a tight, light-resistant container.

Spill Response Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage using high efficiency vacuum cleaner. Avoid breathing dust.

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

Section 7. Exposure controls and 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.

Section 8. 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
Percentage 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 soluble in 10 % ethanol.

Section 9. Physical Hazards

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 10. 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 tablet.
Other	-

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

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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.