NEXTOP

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Abbreviated Prescribing information for NEXTOP (Topiramate 25 mg, 50 mg and 100 mg Tablets)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Topiramate is a sulfamate-substituted monosaccharide. Electrophysiological and biochemical evidence suggests that topiramate, at pharmacologically relevant concentrations, blocks voltage-dependent sodium channels, augments the activity of the neurotransmitter gammaaminobutyrate at some subtypes of the GABA-A receptor.

INDICATIONS: Epilepsy: indicated as adjunctive therapy for adults and pediatric patients 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. **Migraine:** for adults for the prophylaxis of migraine headache.

DOSAGE AND ADMINISTRATION: Epilepsy: the addition of topiramate to phenytoin may require an adjustment of the dose of phenytoin. addition or withdrawal of phenytoin and/or carbamazepine may require adjustment of the dose of topiramate. patients with renal impairment: one half of the usual adult dose is recommended. geriatric patients: dosage adjustment may be indicated in the elderly patient when impaired renal function. patients undergoing hemodialysis: to avoid rapid drops in topiramate plasma concentration during hemodialysis, a supplemental dose of topiramate may be required. patients with hepatic disease: topiramate plasma concentrations may be increased.

CONTRAINDICATION: In patients with a history of hypersensitivity to any component of this product.

WARNINGS & PRECAUTIONS: Acute Myopia and Secondary Angle Closure Glaucoma has been reported. Visual field defects have been reported. Topiramate, increase the risk of suicidal thoughts or behavior in patients. Oligohidrosis, infrequently resulting in hospitalization, has been reported. Decreased sweating and an elevation in body temperature above normal characterized these cases.
Topiramate should be withdrawn gradually to minimize the potential of increased seizure frequency. Cognitive related dysfunction (e.g. confusion, psychomotor slowing, difficulty with concentration/attention, difficulty with memory, speech or language problems, particularly wordfinding difficulties) and Psychiatric/behavioral disturbances (e.g. depression or mood problems). Somnolence and fatigue were reported. Hyperchloremic, non-anion gap, metabolic acidosis is associated with topiramate treatment. During the course of premarketing development of topiramate tablets, 10 sudden and unexplained deaths were recorded. Hyperammonemia has also been observed in patients who were taking topiramate with or without concomitant valproic acid.

DRUG INTERACTIONS: Topiramate in combination with hydrochlorothiazide, pioglitazone, risperidone, digoxin, cns depressants, oral contraceptives, metformin, lithium, haloperidol, amitriptyline, sumatriptan, glyburide, diltiazem, dihydroergotamine and other carbonic anhydrase inhibitors.

ADVERSE REACTIONS: Dizziness, ataxia, speech disorders and related speech problems, psychomotor slowing, abnormal vision, difficulty with memory, paresthesia, diplopia, nervousness, difficulty with concentration or attention, confusion, depression, anorexia, language problems, anxiety,

mood problems, weight decrease, anorexia, nervousness, and difficulty with concentration /attention, difficulty with memory, aggressive reaction, weight decrease, anxiety, difficulty with concentration or attention, paresthesia, syncope, arthralgia, impotence, hallucination, psychosis, suicide attempt, anemia, conjunctivitis, bullous skin reactions (including erythema multiforme, Stevens- Johnson syndrome, toxic epidermal necrolysis), hepatic failure (including fatalities), hepatitis, maculopathy, pancreatitis, and pemphigus.

MARKETED BY:

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IN/ NEXTOP 25, 50 100 mg/APR 2021/07/ABPI

(Additional information is available on request)