Topiramate tablets are indicated as initial monotherapy in patients 2 years of age and older with partial onset seizures, with or without secondary generalized seizures, with or without primary generalized tonic-clonic seizures.

**Dosage and Administration (2)**

**Patients 2 Years of Age and Older**

The recommended initial dose for topiramate tablets is 25 mg/day in the morning and 25 mg/day in the evening. The dose can be increased by 25 mg/day at weekly intervals until a seizure-free dose is achieved or until the maximum dose of 500 mg/day is reached. The maintenance dose of topiramate tablets should be reduced to the lowest dose possible to achieve seizure control.

**Pediatric Patients**

Topiramate tablets are not indicated for partial onset seizures in pediatric patients less than 2 years of age. If left untreated,

**Metabolic Acidosis**

Metabolic acidosis may have harmful effects on your baby. Talk to your healthcare provider if you are pregnant or planning to become pregnant.

**Hypothermia**

Hypothermia has been reported with and without anticonvulsant therapy.

**Topiramate Tablets**

Topiramate tablets are available in 25 mg, 50 mg, and 100 mg tablets.

**DOSAGE FORMS AND STRENGTHS**

**Table 5**

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Adult</th>
<th>Pediatric 6-11 Years</th>
<th>Pediatric 12-17 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feeling tired</td>
<td>3%</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Nervousness</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Somnolence</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
</tr>
</tbody>
</table>

**Additional Drug Monitoring**

**Blood COUNT**

Hematologic values may be affected by topiramate therapy. Monitor hematologic values during therapy and adjust dose as necessary.

**Chemistry**

Monitor chemistry values during therapy and adjust dose as necessary.

**Physiologic Changes**

Topiramate may cause normal laboratory values to be outside the normal range. Monitor laboratory values during therapy and adjust dose as necessary.

**Patient Counseling Information (17)**

Tell your healthcare provider about the medications you take, including prescription and over-the-counter medications, vitamins, and herbal products.

**What to Avoid**

Do not take topiramate tablets if you are pregnant or planning to become pregnant.

**When to Call Your Healthcare Provider**

Call your healthcare provider if you experience any of the following:

- Feeling tired
- Dizziness
- Nervousness
- Somnolence

**Other Information**

Store topiramate tablets at room temperature in a tightly closed container.

**REFERENCES**

- FDA approval package insert
- Clinical trial data
Dizziness or loss of muscle coordination.

How should I store topiramate tablets?

- Keep the bottle tight closed.
- Store at 20°C to 25°C (68°F to 77°F) [See USP controlled room temperature].
- Protect from moisture.
- Do not freeze.

Topiramate is a sulfamate-substituted monosaccharide. Topiramate tablets USP are available as 25mg, 50mg, and 100mg.

Manufactured for: Cipla USA, Inc.

Store at 20°C to 25°C (68°F to 77°F) [See USP controlled room temperature]. Protect from moisture. Do not freeze.