Alprazolam Tablets, USP

Alprazolam is a white or off-white crystal-like powder, which is soluble in ethanol or methanol. Each Alprazolam Tablet contains the following inactive ingredients: lactose, microcrystalline cellulose, starch, magnesium stearate, and titanium dioxide. The tablets are imprinted with "ALPRAZOLAM 0.5" and are scored with "0.5" in one direction and "ALPRAZOLAM 1.0" and are scored with "1.0" in the other direction. Dosage forms are supplied in bottles of 100 tablets (NDC 0059-0091-10), 500 tablets (NDC 0059-0091-50), and 1000 tablets (NDC 0059-0091-45).

For all users of ALPRAZOLAM:

- Inform patients that ALPRAZOLAM may cause drowsiness or dizziness. Advise patients to avoid driving or other activities requiring alertness until they are sure they are not affected by the drug.
- Inform patients that ALPRAZOLAM may impair short-term and long-term memory. Inform patients that the use of alcohol or other CNS depressant drugs should be avoided while taking ALPRAZOLAM.
- Inform patients that the use of other medications that may interact with ALPRAZOLAM requires careful consideration. Patients should be advised to inform their physician or other health care professional about all medications they are taking or plan to take.
- Inform patients that the use of ALPRAZOLAM, particularly at high doses or for long periods of time, may impair physical and mental skills required to perform potentially hazardous tasks, such as driving a car or operating machinery.
- Inform patients that the use of ALPRAZOLAM may impair the ability to perform tasks requiring alertness, such as driving a car or operating machinery.

Dosage Forms:

- Tablets: Each 0.5 mg tablet contains alprazolam 0.5 mg, lactose, microcrystalline cellulose, starch, magnesium stearate, and titanium dioxide.
- Tablets: Each 1.0 mg tablet contains alprazolam 1.0 mg, lactose, microcrystalline cellulose, starch, magnesium stearate, and titanium dioxide.

Alprazolam is available in tablets of 0.5 mg, 1.0 mg, and 2.0 mg.

Indications:

- Anxiety Disorders
- Major Depressive Disorder
- Panic Disorder
- Social Anxiety Disorder
- Generalized Anxiety Disorder
### DISCONTINUATION-EMERGENT SYMPTOMS

#### Incidence of Involuntary Emergence of Abnormal Symptoms

<table>
<thead>
<tr>
<th>Condition</th>
<th>ALPRAZOLAM (%)</th>
<th>PLACEBO (%)</th>
<th>ALPRAZOLAM (%)</th>
<th>PLACEBO (%)</th>
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</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>16.6</td>
<td>24.9</td>
<td>4.9</td>
<td>6.3</td>
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<tr>
<td>Depression</td>
<td>13.9</td>
<td>14.0</td>
<td>1.2</td>
<td>1.3</td>
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<tr>
<td>Fatigue and Tiredness</td>
<td>4.2</td>
<td>5.3</td>
<td>4.2</td>
<td>5.3</td>
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<tr>
<td>Tremor</td>
<td>3.0</td>
<td>0.6</td>
<td>5.8</td>
<td>0.2</td>
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<tr>
<td>Geriatric Symptoms</td>
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<td>7.7</td>
<td>2.9</td>
<td>7.7</td>
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<tr>
<td>Dry Mouth</td>
<td>14.7</td>
<td>13.3</td>
<td>11.4</td>
<td>0.9</td>
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<tr>
<td>Constipation</td>
<td>26.2</td>
<td>15.4</td>
<td>7.6</td>
<td>10.9</td>
</tr>
<tr>
<td>Increased Libido</td>
<td>7.7</td>
<td>4.1</td>
<td>7.7</td>
<td>4.1</td>
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<tr>
<td>Incontinence</td>
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<td>1.5</td>
<td>0.6</td>
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<td>Confusional State</td>
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<td>8.2</td>
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<td>Derealization</td>
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<td>1.9</td>
<td>1.2</td>
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<tr>
<td>Dizziness</td>
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<td>1.3</td>
<td>1.2</td>
<td>1.3</td>
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<tr>
<td>Nausea/Vomiting</td>
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<td>11.4</td>
<td>0.9</td>
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<td>Abnormal Involuntary Movement</td>
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<td>27.5</td>
<td>29.5</td>
<td>27.5</td>
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<tr>
<td>Spasticity</td>
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<td>10.6</td>
<td>6.9</td>
<td>10.6</td>
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<td>Sleep Disturbances</td>
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<td>7.5</td>
<td>25.2</td>
<td>7.5</td>
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<tr>
<td>Hallucinations</td>
<td>8.1</td>
<td>9.3</td>
<td>8.1</td>
<td>9.3</td>
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</tbody>
</table>

### Treatment-Emergent Adverse Events Reported in Placebo-Controlled Trials of Panic Disorder

#### Treatment-Emergent Adverse Events

- **Intolerance**
  - **Gastrointestinal**
    - **Nausea/Vomiting**: 15.6%
    - **Diarrhea**: 10.6%
  - **Nervous System**:
    - **Vomiting**: 15.6%
    - **Drowsiness**: 10.6%
  - **Respiratory System**:
    - **Nasal Congestion**: 15.6%
    - **Sinusitis**: 15.6%
    - **Nasal Obstruction**: 15.6%
  - **Skin**:
    - **Rash**: 15.6%
  - **Eye**:
    - **Eye Obstruction**: 15.6%

- **Other**
  - **Constitutional Special Sensations**: 15.6%
  - **Metabolic and Nutritional**:
    - **Weight Gain**: 2.7%
  - **Neurologic**:
    - **Back Pain**: 15.6%
  - **Gastrointestinal**:
    - **Constipation**: 15.6%
  - **Musculoskeletal**:
    - **Back Pain**: 15.6%
  - **Respiratory**:
    - **Wheeze**: 15.6%

### Treatment-Discontinuation Adverse Events Reported in Placebo-Controlled Trials of Panic Disorder

#### Treatment-Discontinuation Adverse Events

- **Intolerance**
  - **Gastrointestinal**
    - **Nausea/Vomiting**: 15.6%
    - **Diarrhea**: 10.6%
  - **Nervous System**:
    - **Vomiting**: 15.6%
    - **Drowsiness**: 10.6%
  - **Respiratory System**:
    - **Nasal Congestion**: 15.6%
    - **Sinusitis**: 15.6%
    - **Nasal Obstruction**: 15.6%
  - **Skin**:
    - **Rash**: 15.6%
  - **Eye**:
    - **Eye Obstruction**: 15.6%

- **Other**
  - **Constitutional Special Sensations**: 15.6%
  - **Metabolic and Nutritional**:
    - **Weight Gain**: 2.7%
  - **Neurologic**:
    - **Back Pain**: 15.6%
  - **Gastrointestinal**:
    - **Constipation**: 15.6%
  - **Musculoskeletal**:
    - **Back Pain**: 15.6%
  - **Respiratory**:
    - **Wheeze**: 15.6%

### Treatment-Discontinuation Adverse Events Reported in Placebo-Controlled Trials of Panic Disorder

#### Treatment-Discontinuation Adverse Events

- **Intolerance**
  - **Gastrointestinal**
    - **Nausea/Vomiting**: 15.6%
    - **Diarrhea**: 10.6%
  - **Nervous System**:
    - **Vomiting**: 15.6%
    - **Drowsiness**: 10.6%
  - **Respiratory System**:
    - **Nasal Congestion**: 15.6%
    - **Sinusitis**: 15.6%
    - **Nasal Obstruction**: 15.6%
  - **Skin**:
    - **Rash**: 15.6%
  - **Eye**:
    - **Eye Obstruction**: 15.6%

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    - **Back Pain**: 15.6%
  - **Respiratory**:
    - **Wheeze**: 15.6%

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#### Treatment-Discontinuation Adverse Events

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  - **Nervous System**:
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    - **Wheeze**: 15.6%