Interference With Cognitive and Motor Performance: patients with open angle glaucoma who are receiving appropriate therapy but is contraindicated (12) paresthesias (numbness or tingling sensations); (13) chills or hot flushes.

Panic Disorder: compared to 37% of placebo-treated patients. 4 mg/day or placebo. This study was conducted in three phases: a 1-week placebo lead-in, a 1 mg dose group and placebo in reduction from baseline in the number of full panic attacks was

Clinical Trials: will impair clonazepam elimination. Thus, caution should be exercised when administering clonazepam are reached within 1 to 4 hours after oral administration. Clonazepam is approx-

Chemically, clonazepam is 5-(2-chlorophenyl)-1,3-dihydro-7-nitro-2,3-dioxide, sorbitol, sodium lauryl sulfate, and talc.

Table 1 shows absolute and relative risk by indication for all evaluated AEDs.

a range of indications suggests that the risk applies to all AEDs used for any indication. The risk

11 different AEDs showed that patients randomized to one of the AEDs had approximately 27,863 AED-treated patients was 0.43% compared to 0.24% among 16,029 placebo-treated

In children of women treated with drugs for epilepsy, reports suggesting an elevated incidence

pregnancy.

concern should be reported immediately to healthcare providers.

Patients, their caregivers, and families should be informed that AEDs increase the risk of sui-

Anyone considering prescribing clonazepam or any other AED must balance the risk of suicidal

for the epilepsy and psychiatric indications.

WARNINGS, PRECAUTIONS

1. Clonazepam can slow your thinking and motor skills:

• Do not drive, operate heavy machinery, or do other dangerous activities until you know how clonazepam affects you.

• Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking clonazepam until you talk to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, clonazepam may make your sleepiness or dizziness worse.

Do not stop taking clonazepam without first talking to your healthcare provider.

Stopping clonazepam suddenly can cause serious problems.

Clonazepam can cause serious side effects, including:

1. Clonazepam can slow your thinking and motor skills:

2. Clonazepam can cause withdrawal symptoms:

3. Clonazepam may harm your unborn or developing baby:

• If you take clonazepam during pregnancy, your baby is at risk for serious birth defects. These defects can happen as early as in the first month of pregnancy, even before you know you are pregnant. Birth defects may occur more often in women who are taking 10 mg of clonazepam or more.

• Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

• Suicide thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

Do not stop clonazepam without first talking to a healthcare provider.

Stopping clonazepam suddenly can cause seizures and other serious problems. Stopping clonazepam can cause withdrawal symptoms and, in some cases, may precipitate status epilepticus.

4. Clonazepam can cause abuse and dependence:

Do not let other people take your medicine. Stopping clonazepam suddenly can cause seizures, especially if you have taken clonazepam for a long time or in high doses. Stopping clonazepam suddenly can cause seizures and other serious problems. Stopping clonazepam suddenly can cause withdrawal symptoms and, in some cases, may precipitate status epilepticus.

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Tell your healthcare provider about all the medicines you take, both prescription and nonprescription (over-the-counter OTC) medicines, vitamins, and herbal or other supplements. Taper clonazepam with certain other medicines can cause side effects. You should never stop taking clonazepam without first talking to your healthcare provider because stopping clonazepam suddenly can affect how well you work. Do not start or stop other medicines without talking to your healthcare provider.

Know the ingredients you take. Keep a list of all the medicines you take showing to your healthcare provider and pharmacist when you get a new medicine.

**How should I take Clonazepam Orally Disintegrating Tablets?**

- **Take Clonazepam Orally Disintegrating Tablets exactly as your healthcare provider tells you.** Clonazepam Orally Disintegrating Tablets are available as a tablet or as an orally disintegrating tablet.
- **Do not stop taking Clonazepam Orally Disintegrating Tablets without first talking to your healthcare provider.** Stopping clonazepam orally disintegrating tablets suddenly can cause serious problems.
- **Do not take more than the recommended dose of Clonazepam Orally Disintegrating Tablets.** The recommended dose is 0.5 to 4 mg/day in divided doses. Do not use more than 4 mg/day.
- **Do not take orally disintegrating tablets through the foil.** After opening the blister pack, take the orally disintegrating tablet and place it in your mouth.
- **Do not chew or suck on the tablet.** If you take too much Clonazepam Orally Disintegrating Tablets, call your healthcare provider or local Poison Control Center right away.

**What should I avoid while taking Clonazepam Orally Disintegrating Tablets?**

- **Clonazepam can slow your thinking and motor skills.** Do not drive, operate heavy machinery, or do other activities that require alertness until you know how clonazepam affects you.
- **Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking clonazepam.** Before you begin taking clonazepam, talk to your healthcare provider about the risks of drinking alcohol or using street drugs while taking clonazepam. Clonazepam may make your sleepiness or dizziness worse.

**What are the possible side effects of Clonazepam Orally Disintegrating Tablets?**

- **See “What is the most important information I should know about Clonazepam Orally Disintegrating Tablets?”**
- **Clonazepam can also make your seizures happen more often or make them worse.** Call your healthcare provider right away if your seizures get worse while taking clonazepam.
- **These are all possible side effects of clonazepam intake:**
  - driedness
  - problems with walking and coordination
  - dizziness
  - depression
  - fatigue
  - problems with memory

**These are all the possible side effects of clonazepam. For more information, ask your healthcare provider or pharmacist.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or report them to PAR PHARMACEUTICALS at 1-828-9393.

**How should I store Clonazepam Orally Disintegrating Tablets?**

- Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

**Do not freeze.**

**Keep Clonazepam Orally Disintegrating Tablets and all medicines out of the reach of children.**

**General Information about Clonazepam Orally Disintegrating Tablets**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use clonazepam for a condition for which it was not prescribed. Do not give clonazepam to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Clonazepam Orally Disintegrating Tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about clonazepam that is written for health professionals.

For more information, go to www.parpharm.com or call 1-828-9393.

**What are the ingredients in Clonazepam Orally Disintegrating Tablets?**

Active ingredient: clonazepam

Inactive ingredients:
- Tablets
  - 0.25 mg tablets contain: crospovidone, magnesium stearate, monilid, silicon dioxide, sorbitol, sodium lauryl sulfate and lac
  - 0.5 mg tablets contain: crospovidone, magnesium stearate, monilid, silicon dioxide, sorbitol, sodium lauryl sulfate and lac
  - 0.75 mg tablets contain: crospovidone, magnesium stearate, monilid, silicon dioxide, sorbitol, sodium lauryl sulfate and lac
  - 1 mg tablets contain: crospovidone, magnesium stearate, monilid, silicon dioxide, sorbitol, sodium lauryl sulfate and lac
  - 1.5 mg tablets contain: crospovidone, magnesium stearate, monilid, silicon dioxide, sorbitol, sodium lauryl sulfate and lac
  - 2 mg tablets contain: crospovidone, magnesium stearate, monilid, silicon dioxide, sorbitol, sodium lauryl sulfate and lac

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by PAR PHARMACEUTICALS
Chestnut Ridge, NY 10977

For additional copies of this Medication Guide, visit www.parpharm.com or call 1-828-9393.