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Medication Guide

KLONOPIN® (KLON-oh-pin)

(clonazepam)

Tablets and Wafers



Read this Medication Guide before you start taking KLONOPIN and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

KLONOPIN can cause serious side effects. Because stopping KLONOPIN suddenly can also cause serious problems, do not stop taking KLONOPIN without talking to your healthcare provider first.

What is the most important information I should know about KLONOPIN?

Do not stop taking KLONOPIN without first talking to your healthcare provider. Stopping KLONOPIN suddenly can cause serious problems.

KLONOPIN can cause serious side effects, including:

1. KLONOPIN can slow your thinking and motor skills

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how KLONOPIN affects you.
- Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking KLONOPIN until you talk to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, KLONOPIN may make your sleepiness or dizziness worse.

2. Like other antiepileptic drugs, KLONOPIN may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempt to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

40 **How can I watch for early symptoms of suicidal thoughts and actions?**

41 • Pay attention to any changes, especially sudden changes, in mood,
42 behaviors, thoughts, or feelings.

43 • Keep all follow-up visits with your healthcare provider as scheduled.

44 Call your healthcare provider between visits as needed, especially if you are
45 worried about symptoms.

46
47 Suicidal thoughts or actions can be caused by things other than medicines. If
48 you have suicidal thoughts or actions, your healthcare provider may check
49 for other causes.

50 **Do not stop KLONOPIN without first talking to a healthcare provider.**

51 Stopping KLONOPIN suddenly can cause serious problems. Stopping
52 KLONOPIN suddenly can cause seizures that will not stop (status
53 epilepticus).

54 **3. KLONOPIN may harm your unborn or developing baby.**

55 • If you take KLONOPIN during pregnancy, your baby is at risk for serious
56 birth defects. These defects can happen as early as in the first month of
57 pregnancy, even before you know you are pregnant. Birth defects may
58 occur even in children born to women who are not taking any medicines
59 and do not have other risk factors.

60 • Children born to mothers receiving benzodiazepine medications (including
61 KLONOPIN) late in pregnancy may be at some risk of experiencing
62 breathing problems, feeding problems, hypothermia, and withdrawal
63 symptoms.

64 • Tell your healthcare provider right away if you become pregnant while
65 taking KLONOPIN. You and your healthcare provider should decide if
66 you will take KLONOPIN while you are pregnant.

67 • If you become pregnant while taking KLONOPIN, talk to your healthcare
68 provider about registering with the North American Antiepileptic Drug
69 Pregnancy Registry. You can register by calling 1-888-233-2334. The
70 purpose of this registry is to collect information about the safety of
71 antiepileptic drugs during pregnancy.

72 • KLONOPIN can pass into breast milk. Talk to your healthcare provider
73 about the best way to feed your baby if you take KLONOPIN. You and
74 your healthcare provider should decide if you will take KLONOPIN or
75 breast feed. You should not do both.

76 **4. KLONOPIN can cause abuse and dependence.**

77 • Do not stop taking KLONOPIN all of a sudden. Stopping KLONOPIN
78 suddenly can cause seizures that do not stop, hearing or seeing things that
79 are not there (hallucinations), shaking, and stomach and muscle cramps.

- 80 ○ Talk to your doctor about slowly stopping KLONOPIN to avoid
- 81 getting sick with withdrawal symptoms.
- 82 ○ Physical dependence is not the same as drug addiction. Your
- 83 healthcare provider can tell you more about the differences
- 84 between physical dependence and drug addiction.

85 **KLONOPIN is a federally controlled substance (C-IV) because it can be**
86 **abused or lead to dependence. Keep KLONOPIN in a safe place to prevent**
87 **misuse and abuse. Selling or giving away KLONOPIN may harm others, and**
88 **is against the law. Tell your doctor if you have ever abused or been**
89 **dependent on alcohol, prescription medicines or street drugs.**

90 **What is KLONOPIN?**

91 KLONOPIN is a prescription medicine used alone or with other medicines to
92 treat:

- 93 • certain types of seizure disorders (epilepsy) in adults and children
- 94 • panic disorder with or without fear of open spaces (agoraphobia) in adults

95 It is not known if KLONOPIN is safe or effective in treating panic disorder in
96 children younger than 18 years old.

97 **Who should not take KLONOPIN?**

98 Do not take KLONOPIN if you:

- 99 • are allergic to benzodiazepines
- 100 • have significant liver disease
- 101 • have an eye disease called acute narrow angle glaucoma

102 **Ask your healthcare provider if you are not sure if you have any of the**
103 **problems listed above.**

104 **What should I tell my healthcare provider before taking KLONOPIN?**

105 Before you take KLONOPIN, tell your healthcare provider if you:

- 106 • have liver or kidney problems
- 107 • have lung problems (respiratory disease)
- 108 • have or have had depression, mood problems, or suicidal thoughts or
- 109 behavior
- 110 • have any other medical conditions

111
112 **Tell your healthcare provider about all the medicines you take, including**
113 **prescription and non-prescription medicines, vitamins, and herbal supplements.**
114 **Taking KLONOPIN with certain other medicines can cause side effects or affect**

115 how well they work. Do not start or stop other medicines without talking to your
116 healthcare provider.

117 Know the medicines you take. Keep a list of them and show it to your healthcare
118 provider and pharmacist when you get a new medicine.

119 **How should I take KLONOPIN?**

- 120 • Take KLONOPIN exactly as your healthcare provider tells you.
121 KLONOPIN is available as a tablet or as an orally disintegrating tablet
122 (wafer).
- 123 • Do not stop taking KLONOPIN without first talking to your healthcare
124 provider. Stopping KLONOPIN suddenly can cause serious problems.
- 125 • **KLONOPIN tablets** should be taken with water and swallowed whole.
- 126 • **KLONOPIN wafers** can be taken with or without water.
 - 127 ○ Do not open the pouch until you are ready to take KLONOPIN.
 - 128 ○ After opening the pouch, peel back the foil on the blister pack.
 - 129 ○ Do not push the wafer through the foil.
 - 130 ○ After opening the blister pack, with dry hands, take the wafer and
131 place it in your mouth.
 - 132 ○ The wafer will melt quickly.
- 133 • If you take too much KLONOPIN, call your healthcare provider or local
134 Poison Control Center right away.

135 **What should I avoid while taking KLONOPIN?**

- 136 • KLONOPIN can slow your thinking and motor skills. Do not drive,
137 operate heavy machinery, or do other dangerous activities until you know
138 how KLONOPIN affects you.
- 139 • Do not drink alcohol or take other drugs that may make you sleepy or
140 dizzy while taking KLONOPIN until you talk to your healthcare
141 provider. When taken with alcohol or drugs that cause sleepiness or
142 dizziness, KLONOPIN may make your sleepiness or dizziness worse.

143 **What are the possible side effects of KLONOPIN?**

144 See “**What is the most important information I should know about**
145 **KLONOPIN?**”

146 KLONOPIN can also make your seizures happen more often or make them worse.
147 Call your healthcare provider right away if your seizures get worse while taking
148 KLONOPIN.

149 The most common side effects of KLONOPIN include:

- 150 • Drowsiness
- 151 • Problems with walking and coordination
- 152 • Dizziness

- 153 • Depression
- 154 • Fatigue
- 155 • Problems with memory

156 These are not all the possible side effects of KLONOPIN. For more information,
157 ask your healthcare provider or pharmacist.

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

160 Call your doctor for medical advice about side effects. You may report side
161 effects to FDA at 1-800-FDA-1088 or Genentech at 1-888-835-2555.

162 **How should I store KLONOPIN?**

- 163 • Store KLONOPIN between 59°F to 86°F (15°C to 30°C)

164 **Keep KLONOPIN and all medicines out of the reach of children.**

165 **General Information about KLONOPIN**

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

170 This Medication Guide summarizes the most important information about
171 KLONOPIN. If you would like more information, talk with your healthcare
172 provider. You can ask your pharmacist or healthcare provider for information
173 about KLONOPIN that is written for health professionals.

174 For more information, go to www.gene.com/gene/products/information/klonopin
175 or call 1-888-835-2555.

176 **What are the ingredients in KLONOPIN?**

177 Active ingredient: clonazepam

178 Inactive ingredients:

- 179 • Tablets:
 - 180 ○ 0.5 mg tablets contain lactose, magnesium stearate,
181 microcrystalline cellulose, corn starch, FD&C Yellow No. 6 Lake
 - 182 ○ 1 mg tablets contain lactose, magnesium stearate, microcrystalline
183 cellulose, corn starch, FD&C Blue No. 1 Lake and FD&C Blue
184 No. 2 Lake
 - 185 ○ 2 mg tablets contain lactose, magnesium stearate, microcrystalline
186 cellulose, corn starch
- 187 • Wafers: gelatin, mannitol, methylparaben sodium, propylparaben sodium
188 and xanthan gum
- 189

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192 Administration.

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198 www.gene.com/gene/products/information/klonopin.