KLOPION® TABLETS
(Klonopin® Tablets) (spray-dried)

WARNINGS: RISK FACTORS FOR CONSTATECIOUSness WITH OPIATES AND PHENOTHIAZINES. Addictive properties and habituation may lead to physical dependence. The above warnings are not exhaustive of the drug’s safety risks. Other warnings, such as those related to the risk of addiction, should also be considered.

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The initial dose for adults with seizure disorders should not exceed 0.5 mg/day divided into three doses. If seizures are not controlled after 1 week, the dose should be increased in increments of 0.5 to 1 mg/day at weekly intervals as needed. The maximum recommended daily dose is 1.5 mg/day. The use of multiple antiepileptic drugs may result in an increase in adverse drug effects. This should be considered before adding clonazepam to an existing antiepileptic regimen.

Neonates and Infants: Because of the risk of withdrawal symptoms, is not recommended for use in neonates and infants. There is no clinical experience with clonazepam in seizure disorder patients younger than 2 months of age.

Pregnancy: Use during pregnancy may be associated with an increased risk of congenital malformations. There are no adequate and well-controlled studies in pregnant women. It is not known if clonazepam crosses the placenta or is excreted in breast milk. Studies in rats indicate that clonazepam may produce fetal abnormalities at doses that were lethal to the mother. If clonazepam is used in pregnancy, or if the patient becomes pregnant while taking the drug, the patient should be apprised of the potential risk to the fetus. Women should be advised to notify their physician if they become pregnant while taking the drug. Contraception should be taken into consideration during treatment with clonazepam.

Pediatric Use: The use of clonazepam in children younger than 18 years of age has not been established. Therefore, since clonazepam is associated with serious and sometimes fatal adverse events and is not necessary for the management of seizures in children, its use in children younger than 18 years of age is not recommended.

Geriatric Use: In general, elderly patients should be started on lower doses of clonazepam. The dose should be titrated gradually.

Allergic Reactions: Clonazepam has been reported to cause allergic reactions including anaphylaxis. Patients with history of a previous allergic reaction to clonazepam should be monitored carefully.

Drug Interactions: When clonazepam is used either alone or in combination with other antiepileptic drugs, the dose should be reduced gradually. If clonazepam is used in combination with diazepam, increased doses may be necessary.

Flumazenil is not indicated in patients with epilepsy who have been treated with benzodiazepines. Therefore, flumazenil should be used with caution in patients with a history of seizure disorder, especially those with a history of status epilepticus. Flumazenil is contraindicated in patients with a history of severe hypersensitivity reactions to benzodiazepines. Flumazenil should not be used to reverse the sedative, analgesic, or anesthetic effects of benzodiazepines. Flumazenil should be used with caution in patients with hepatic or renal impairment, elderly patients, and in cases of serious status epilepticus because the response to benzodiazepines may be altered in these patients.

If you are not sure if you have any of these symptoms, it may harm them. Check with your healthcare provider if you have the same symptoms that you have. It may harm them.

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

- Pay attention to any changes—especially sudden changes—in mood, behavior, thoughts, or feelings.

- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you are concerned about your mental health.

How should I store KLONOPIN?

- Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).

- Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking KLONOPIN or other benzodiazepines. KLONOPIN tablets should be taken with water and swallowed whole. Do not cut, break, chew, or crush KLONOPIN tablets. KLONOPIN tablets should not be taken with milk or dairy products.

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how KLONOPIN affects you. If you have any of the problems listed above, you should not drive, operate heavy machinery, or do other dangerous activities.

- Do not take KLONOPIN if you:
  - have liver or kidney problems
  - have lung problems (respiratory disease)
  - have or had depression, mood problems, or suicidal thoughts or behavior.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking KLONOPIN with other medicines can cause side effects or affect how well KLONOPIN or other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

KLONOPIN tablets are available as scored tablets with a K-shaped perforation—0.5 mg tablets contain lactose, magnesium stearate, microcrystalline cellulose, corn starch, FD&C Yellow No. 1 Lake, and FD&C Blue No. 2 Lake; 1 mg tablets contain lactose, microcrystalline cellulose, sodium croscarmellose, corn starch, FD&C Blue No. 1 Lake and FD&C Blue No. 2 Lake; 2 mg tablets contain lactose, microcrystalline cellulose, sodium croscarmellose, corn starch, and lactose monohydrate.

KLONOPIN is a benzodiazepine medicine. Benzodiazepines can make you sleepy or dizzy and can slow your thinking and motor skills. This may get better over time.

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  - have liver or kidney problems
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