

MEDICATION GUIDE
SYMPAZAN™ (SYM-pa-zan)
(clobazam)
oral film, CIV

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

- **Do not stop taking SYMPAZAN without first talking to your healthcare provider.** Stopping SYMPAZAN suddenly can cause serious side effects.
- **SYMPAZAN is a benzodiazepine medicine. Benzodiazepines can cause severe drowsiness, breathing problems (respiratory depression), coma, and death when taken with opioid medicines.**
- **SYMPAZAN can make you sleepy or dizzy and can slow your thinking and motor skills. This may get better over time.**
 - Do not drive, operate heavy machinery, or do other dangerous activities until you know how SYMPAZAN affects you.
 - SYMPAZAN may cause problems with your coordination, especially when you are walking or picking things up.
- **Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking SYMPAZAN until you talk to your healthcare provider.** When taken with alcohol or drugs that cause sleepiness or dizziness, SYMPAZAN may make your sleepiness or dizziness much worse.
- **SYMPAZAN can cause withdrawal symptoms.**
 - Do not stop taking SYMPAZAN all of a sudden without first talking to a healthcare provider. Stopping SYMPAZAN suddenly can cause seizures that will not stop (status epilepticus), hearing or seeing things that are not there (hallucinations), shaking, nervousness, and stomach and muscle cramps.
 - Talk to your healthcare provider about slowly stopping SYMPAZAN to avoid withdrawal symptoms.
- **SYMPAZAN can be abused and cause dependence.**
 - Physical dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical dependence and drug addiction.
- **SYMPAZAN is a federally controlled substance (CIV) because it can be abused or lead to dependence.** Keep SYMPAZAN in a safe place to prevent misuse and abuse. Selling or giving away SYMPAZAN may harm others, and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- **Serious skin reactions have been seen when SYMPAZAN is taken with other medicines and may require stopping its use.** Do not stop taking SYMPAZAN without first talking to your healthcare provider.
 - A serious skin reaction can happen at any time during your treatment with SYMPAZAN, but is more likely to happen within the first 8 weeks of treatment. These skin reactions may need to be treated right away.
 - Call your healthcare provider immediately if you have skin blisters, rash, sores in mouth, hives or any other allergic reaction.
- **Like other antiepileptic drugs, SYMPAZAN may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.**

Call your 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
- attempts 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

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

- Pay attention to any changes, especially sudden changes, in mood, behaviors, 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 worried about symptoms.

Suicidal 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.

What is SYMPAZAN?

SYMPAZAN is a prescription medicine used along with other medicines to treat seizures associated with Lennox-Gastaut Syndrome in people 2 years of age or older.

It is not known if SYMPAZAN is safe and effective in children less than 2 years old.

Do not take SYMPAZAN if you:

- are allergic to clobazam or any of the ingredients in SYMPAZAN. See the end of this Medication Guide for a complete list of ingredients in SYMPAZAN.

Before you take SYMPAZAN, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems
- have lung problems (respiratory disease)
- have or have had depression, mood problems, or suicidal thoughts or behavior
- use birth control medicine. SYMPAZAN may cause your birth control medicine to be less effective. Talk to your healthcare provider about the best birth control method to use.
- are pregnant or plan to become pregnant. **SYMPAZAN may harm your unborn baby.**
 - Tell your healthcare provider right away if you become pregnant while taking SYMPAZAN. You and your healthcare provider will decide if you should take SYMPAZAN while you are pregnant.
 - Babies born to mothers receiving benzodiazepine medications (including SYMPAZAN) late in pregnancy may be at some risk of experiencing breathing problems, feeding problems, dangerously low body temperature, and withdrawal symptoms.
- If you become pregnant while taking SYMPAZAN, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can register by calling 1-888-233-2334. For more information about the registry go to <http://www.aedpregnancyregistry.org>. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.
- SYMPAZAN can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take SYMPAZAN. You and your healthcare provider should decide if you will take SYMPAZAN or breast feed. You should not do both.

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

How should I take SYMPAZAN?

- Take SYMPAZAN exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much SYMPAZAN to take and when to take it.
- Place the entire SYMPAZAN oral film on top of the tongue.
- SYMPAZAN oral films can be taken with or without food.
- **Do not** take liquids with SYMPAZAN oral films.
- Take only 1 SYMPAZAN oral film at a time.
- Read the **Instructions for Use** at the end of this Medication Guide for information on the right way to take SYMPAZAN™ oral films.
- Your healthcare provider may change your dose if needed. **Do not** change your dose of SYMPAZAN without talking to your healthcare provider.
- **Do not** stop taking SYMPAZAN without first talking to your healthcare provider.
- Stopping SYMPAZAN suddenly can cause serious problems.
- If you take too much SYMPAZAN, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking SYMPAZAN?

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

What are the possible side effects of SYMPAZAN?

SYMPAZAN may cause serious side effects, including:

- See "What is the most important information I should know about SYMPAZAN?"

The most common side effects of SYMPAZAN include:

- sleepiness
- drooling
- constipation
- cough
- pain with urination
- fever
- acting aggressive, being angry, or violent
- difficulty sleeping
- slurred speech
- tiredness
- problems with breathing

These are not all the possible side effects of SYMPAZAN. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SYMPAZAN?

- Store SYMPAZAN oral film between 68°F to 77°F (20°C to 25°C).

Keep SYMPAZAN and all medicines out of the reach of children.

General Information about the safe and effective use of SYMPAZAN.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SYMPAZAN for a condition for which it was not prescribed. Do not give SYMPAZAN to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about SYMPAZAN that is written for health professionals.

What are the ingredients in SYMPAZAN?

Active ingredient: clobazam

Inactive ingredients: artificial cooling flavor, citric acid, glycerol monooleate, hypromellose, maltitol, natural and artificial bitter masker, natural raspberry type flavor, polyethylene oxide, purified water, sodium phosphate dibasic, and sucralose.

Manufactured by:
Aquestive Therapeutics
Warren, NJ 07059

SYMPAZAN™ is a trademark of Aquestive Therapeutics

For more information, go to www.SYMPAZAN.com or call the Aquestive Therapeutics Rx Patient and Caregiver Support Line at 1-833-AQUESTV (1-833-278-3788).

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

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