

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

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

- **SYMPAZAN is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death. Get emergency help right away if any of the following happens:**

- shallow or slowed breathing
- breathing stops (which may lead to the heart stopping)
- excessive sleepiness (sedation)

Do not drive or operate heavy machinery until you know how taking SYMPAZAN with opioids affects you.

- **Risk of abuse, misuse, and addiction.** There is a risk for abuse, misuse, and addiction with benzodiazepines, including SYMPAZAN, which can lead to overdose and serious side effects including coma and death.
 - **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including SYMPAZAN.** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.**
 - **You can develop an addiction even if you take SYMPAZAN as prescribed by your healthcare provider.**
 - **Take SYMPAZAN exactly as your healthcare provider prescribed.**
 - Do not share your SYMPAZAN with other people.
 - Keep SYMPAZAN in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** SYMPAZAN can cause physical dependence and withdrawal reactions.
 - **Do not suddenly stop taking SYMPAZAN.** Stopping SYMPAZAN suddenly can cause serious and life-threatening side effects, including, unusual movements, responses, or expressions, seizures, sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. **Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these symptoms.**
 - **Some people who suddenly stop benzodiazepines have symptoms that can last for several weeks to more than 12 months,** including, anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning, or prickling feeling in your hands, arms, legs or feet, and ringing in your ears.
 - 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.
 - Do not take more SYMPAZAN than prescribed or take SYMPAZAN for longer than prescribed.
- **SYMPAZAN can make you sleepy or dizzy and can slow your thinking and motor skills.**
 - 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 drugs that may make you sleepy or dizzy while taking SYMPAZAN without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, SYMPAZAN may make your sleepiness or dizziness much worse.
- **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 medicines, 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
- new or worse depression
- feeling agitated or restless
- trouble sleeping (insomnia)
- acting aggressive, being angry or violent
- other unusual changes in behavior or mood
- attempts to commit suicide
- new or worse anxiety or irritability
- an extreme increase in activity and talking (mania)
- new or worse panic attacks
- acting on dangerous impulses

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.

Stopping a seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).

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.
- **SYMPAZAN is a federally controlled substance (C-IV) because it contains clobazam that 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.

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?

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

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 at room temperature 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 registered 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).