

MEDICATION GUIDE
ONFI® (ON-fee)
(clobazam)
Tablets and Oral Suspension

Read this Medication Guide before you start taking ONFI 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.

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

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

ONFI can cause serious side effects, including:

- 1. ONFI can make you sleepy or dizzy, slow your thinking, and make you clumsy which may get better over time.**
 - Do not drive, operate heavy machinery, or do other dangerous activities until you know how ONFI affects you.
 - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking ONFI until you talk to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, ONFI may make your sleepiness or dizziness much worse.
- 2. ONFI can cause withdrawal symptoms.**
 - Do not stop taking ONFI all of a sudden without first talking to a healthcare provider. Stopping ONFI 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 ONFI to avoid withdrawal symptoms.
- 3. ONFI 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.

ONFI is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep ONFI in a safe place to prevent misuse and abuse. Selling or giving away ONFI 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.

4. Serious skin reactions have been seen with ONFI and may require stopping its use. Do not stop taking ONFI without first talking to your healthcare provider.

- A serious skin reaction can happen at any time during your treatment with ONFI, but is more likely to happen within the first 8 weeks of treatment. These skin reactions need to be treated right away.
- Call your healthcare provider immediately if you have skin blisters, rash, sores in the mouth, hives or any other allergic reaction.

5. Like other antiepileptic drugs, ONFI 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 ONFI?

ONFI 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 ONFI is safe and effective in children less than 2 years old.

Who should not take ONFI?

Patients with a history of hypersensitivity to ONFI or its ingredients should not take ONFI.

Do not take ONFI if you:

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

What should I tell my healthcare provider before taking ONFI?

Before you take ONFI, tell your healthcare provider if you:

- have liver or kidney problems
- have lung problems (respiratory disease)
- have or have had depression, mood problems, or suicidal thoughts or behavior
- have any other medical conditions
- use birth control medicine. ONFI 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. **ONFI may harm your unborn baby.**
 - o Tell your healthcare provider right away if you become pregnant while taking ONFI. You and your healthcare provider will decide if you should take ONFI while you are pregnant.
 - o Babies born to mothers receiving benzodiazepine medications (including ONFI) 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 ONFI, 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.
- ONFI can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take ONFI. You and your healthcare provider should decide if you will take ONFI 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 ONFI with certain other medicines can cause side effects or affect how well ONFI or the other medications work. Do not start or stop other medicines without talking to your healthcare provider.

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

How should I take ONFI?

- Take ONFI exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much ONFI to take and when to take it.
- ONFI tablets can be taken whole, broken in half along the score, or crushed and mixed in applesauce.
- ONFI tablets and oral suspension can be taken with or without food.
- **Shake the bottle of ONFI oral suspension well right before you take each dose.**
- Measure your dose of ONFI oral suspension using the bottle adapter and dosing syringes that come with your ONFI oral suspension.
- Read the **Instructions for Use** at the end of this Medication Guide for information on the right way to use ONFI oral suspension.
- Your healthcare provider may change your dose if needed. Do not change your dose of ONFI without talking to your healthcare provider.
- Do not stop taking ONFI without first talking to your healthcare provider.
- Stopping ONFI suddenly can cause serious problems.
- If you take too much ONFI, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking ONFI?

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

What are the possible side effects of ONFI?

ONFI may cause serious side effects, including:

See “What is the most important information I should know about ONFI?”

The most common side effects of ONFI 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 ONFI. 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.

How should I store ONFI?

- Store ONFI tablets and oral suspension between 68°F to 77°F (20°C to 25°C).

Tablets

- Keep ONFI tablets in a dry place.

Oral Suspension

- Replace the cap securely after opening.
- Store and dispense ONFI oral suspension in its original bottle in an upright position.
- Use ONFI oral suspension within 90 days of first opening the bottle.
- After 90 days safely throw away any ONFI oral suspension that has not been used.

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

General Information about the safe and effective use of ONFI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ONFI for a condition for which it was not prescribed. Do not give ONFI 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 ONFI. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about ONFI that is written for health professionals.

For more information about ONFI, go to www.lundbeckus.com or call Lundbeck at 1-888-514-5204.

What are the ingredients in ONFI?

Tablets

Active ingredient: clobazam

Inactive ingredients: corn starch, lactose monohydrate, magnesium stearate, silicon dioxide, and talc.

Oral Suspension

Active ingredient: clobazam

Inactive ingredients: magnesium aluminum silicate, xanthan gum, citric acid monohydrate, disodium hydrogen phosphate dihydrate, simethicone emulsion, polysorbate 80, methylparaben, propylparaben, propylene glycol, sucralose, maltitol solution, berry flavor, purified water.

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

Marketed by: Lundbeck, Deerfield, IL 60015, U.S.A.



ONFI is a registered trademark of Lundbeck

12/2014