

MEDICATION GUIDE
LIBERVANT™ (lee-ber-vant)
(diazepam)
buccal film, C-IV

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

- **LIBERVANT 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 allow your child to drive a motor vehicle, operate heavy machinery, or ride a bicycle until you know how taking LIBERVANT with opioids affects your child.
- **Risk of abuse, misuse, and addiction.** LIBERVANT is used in children 2 to 5 years of age. The unapproved use of LIBERVANT has a risk for abuse, misuse, and addiction, 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 diazepam (the active ingredient in LIBERVANT).** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your child's healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.**
 - **Your child can develop an addiction even if your child takes LIBERVANT as prescribed by your child's healthcare provider.**
 - **Give LIBERVANT exactly as your child's healthcare provider prescribed.**
 - Do not share LIBERVANT with other people.
 - Keep LIBERVANT in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** LIBERVANT is intended for use if needed in order to treat higher than usual seizure activity. Benzodiazepines, including LIBERVANT, can cause physical dependence and withdrawal reactions, especially if used daily. LIBERVANT is not intended for daily use.
 - **Do not suddenly stop giving LIBERVANT to your child without talking to your child's healthcare provider.** Stopping LIBERVANT suddenly can cause serious and life-threatening side effects, including, unusual movements, responses, or expressions, seizures that will not stop (status epilepticus), sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, homicidal thoughts, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. **Call your child's healthcare provider or go to the nearest hospital emergency room right away if your child gets 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 child's healthcare provider can tell you more about the differences between physical dependence and drug addiction.

- Do not give your child more LIBERVANT than prescribed or give LIBERVANT more often than prescribed.

- **LIBERVANT can make your child sleepy or dizzy and can slow your child’s thinking and motor skills.**

- Do not allow your child to drive a motor vehicle, operate machinery, or ride a bicycle until you know how LIBERVANT affects your child.
- Do not give other drugs that may make your child sleepy or dizzy while taking LIBERVANT without first talking to your child’s healthcare provider. When taken with drugs that cause sleepiness or dizziness, LIBERVANT may make your child’s sleepiness or dizziness much worse.

Like other antiepileptic medicines, LIBERVANT may cause suicidal thoughts or actions in a small number of people, about 1 in 500.

Call a healthcare provider right away if your child has 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 or irritability
● feeling agitated or restless	● an extreme increase in activity and talking (mania)
● trouble sleeping (insomnia)	
● acting aggressive, being angry or violent	● new or worse panic attacks
● other unusual changes in behavior or mood	● acting on dangerous impulses

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

- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your child’s healthcare provider as scheduled.

Call your child’s 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 your child has suicidal thoughts or actions, your child’s healthcare provider may check for other causes.

What is LIBERVANT?

- LIBERVANT is a prescription medicine used for the short-term treatment of seizure clusters (also known as “acute repetitive seizures”) that are different from a person’s usual seizure pattern in people 2 to 5 years of age.
- **LIBERVANT is a federally controlled substance (C-IV) because it contains diazepam that can be abused or lead to dependence.** Keep LIBERVANT in a safe place to prevent misuse and abuse. Selling or giving away LIBERVANT may harm others and is against the law.

It is not known if LIBERVANT is safe and effective in children less than 2 years of age and over 5 years of age.

Do not give LIBERVANT to your child if your child:

- is allergic to diazepam or any of the ingredients in LIBERVANT. See the end of this Medication Guide for a complete list of ingredients in LIBERVANT.
- has an eye problem called acute narrow angle glaucoma.

Before you give LIBERVANT, tell your child's healthcare provider about all of your child's medical conditions, including if your child:

- has a history of depression, mood problems, or suicidal thoughts or behavior.
- has liver or kidney problems.
- has asthma, emphysema, bronchitis, chronic obstructive pulmonary disease, or other breathing problems.

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

How should I give LIBERVANT?

- **Read the Instructions for Use that comes with this Medication Guide for detailed information about the right way to give LIBERVANT.**
- Give LIBERVANT exactly as your child's healthcare provider tells you to.
- Do not change your child's dosage unless your child's healthcare provider tells you to change it.
- To give LIBERVANT:
 - You as the caregiver must be able to tell the difference between cluster seizures and ordinary seizures.
 - You as the caregiver must be comfortable in your ability to give LIBERVANT as instructed by your child's healthcare provider and as instructed in the Instructions for Use at the end of this Medication Guide.
 - You as the caregiver must understand your child's healthcare provider's instructions about when to use LIBERVANT.
- Your child's healthcare provider will tell you:
 - what seizure clusters are,
 - exactly how much LIBERVANT to give to your child,
 - when to give LIBERVANT,
 - how to give LIBERVANT,
 - what to do after you give LIBERVANT if the seizures do not stop or there is a change in breathing, behavior, or condition that worries you.
- Your child's healthcare provider should show you how to give LIBERVANT the right way.
- You should carry LIBERVANT with you in case you need to give it to treat your child's seizure clusters.
- Before a seizure cluster happens, family members, caregivers, and other people who may have to give LIBERVANT should know where you keep your LIBERVANT and how to give LIBERVANT.
- Each LIBERVANT comes in a sealed foil pouch. Do not open the foil pouch until you are ready to use it.
- **Do not** split LIBERVANT. The entire film should be placed on the inside of the cheek.
- Allow LIBERVANT to dissolve. **Do not** chew or swallow the film.
- Do not take with liquids.
- LIBERVANT can be taken with or without food.
- **What should I do after LIBERVANT has been given:**
 - Note the time LIBERVANT was given and changes in the resting breathing rate.
 - Your child's healthcare provider may prescribe a second dose of LIBERVANT.

- If a second dose is needed, it may be given at least 4 hours after the first dose of LIBERVANT film is given.
- Do not give more than 2 doses of LIBERVANT to treat a seizure cluster.
- Do not give a second dose of LIBERVANT if:
 - you are concerned about your child's breathing,
 - an emergency rescue treatment with breathing help is needed,
 - or there is more sleepiness than normal.

Call for emergency medical help if any of the following happens:

- seizure behavior is different from other episodes the child has had.
- you are alarmed by how often the seizure happens, by how severe it is, by how long it lasts, or seizure is alarming.
- the child has unusual coloring or breathing.
- **Do not** use LIBERVANT for:
 - more than 1 seizure cluster episode every 5 days and
 - more than 5 episodes each month.
- Talk to your child's healthcare provider about slowly stopping LIBERVANT to avoid withdrawal symptoms.
- If you give too much LIBERVANT, call your child's healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of LIBERVANT?

LIBERVANT may cause serious side effects, including:

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

The most common side effects of LIBERVANT are:

- sleepiness
- headache

These are not all the possible side effects of LIBERVANT.

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 LIBERVANT?

- Store LIBERVANT at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep LIBERVANT in the foil pouch until ready to use.
- **Keep LIBERVANT and all medicines out of the reach of children.**

General information about the safe and effective use of LIBERVANT.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LIBERVANT for a condition for which it was not prescribed. Do not give LIBERVANT to other people, even if they have the same symptoms that your child has. It may harm them.

You can ask your pharmacist or healthcare provider for information about LIBERVANT that is written for health professionals.

What are the ingredients in LIBERVANT?

Active ingredient: diazepam

Inactive ingredients: benzyl alcohol, clove oil, EDTA disodium salt, FD&C Green #3, glycerol monooleate, hypromellose, peppermint oil, polyethylene oxide, polyvinylpyrrolidone, sodium phosphate, sucralose, vanillin, xanthan gum, water, and white ink

Manufactured by: Aquestive Therapeutics, Warren NJ 07059, USA

For more information, go to www.aquestive.com or call 1-877-394-5045.

INSTRUCTIONS FOR USE
LIBERVANT™ [lee-ber-vant]
(diazepam) buccal film

Family members, caregivers, and others who may need to administer LIBERVANT should read this Instructions for Use that comes with LIBERVANT before using it.

This Instructions for Use contains information on how to use LIBERVANT. This information does not take the place of talking to your child's healthcare provider about your child's medical condition or your child's treatment. Ask your child's healthcare provider or pharmacist if you or others who may need to administer LIBERVANT have any questions about how to use LIBERVANT the right way.

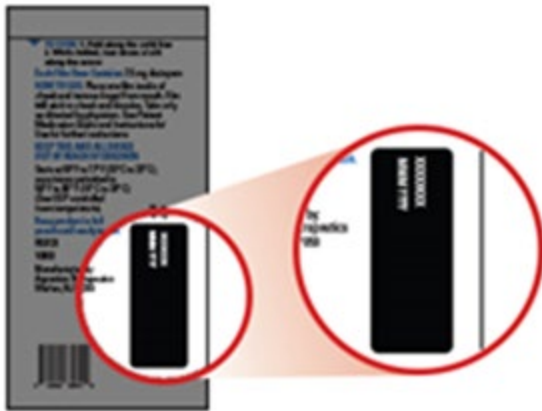
Important Information You Need to Know Before Using LIBERVANT

- For buccal use (place film on inside of cheek)
- Before using LIBERVANT, make sure your child's healthcare provider shows you the right way to use it. If treatment is unable to be given and there is concern, **call for emergency medical help right away.**



Preparing to Use LIBERVANT

- Make sure hands are clean and dry before handling LIBERVANT so the film does not stick to your fingers.
- Check expiration date. **Do not** use if the expiration date has passed.



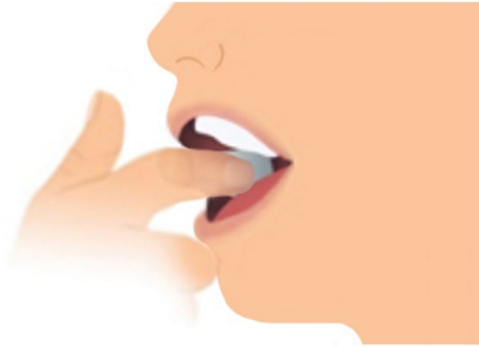
Using LIBERVANT

Step 1. Open Pouch and Remove Film from Pouch



- Fold foil pouch along solid line. While folded over, note where the vertical slit is and carefully tear down the side of the pouch at the slit along the arrow to open the pouch.
- Remove LIBERVANT film from foil pouch. Each foil pouch contains 1 dose of LIBERVANT.

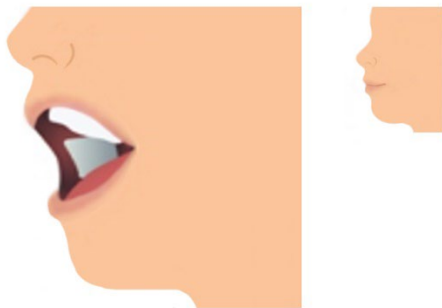
Step 2. Place 1 Film on Inside of Cheek



- **Do not give LIBERVANT film with liquids.**
- Stretch either cheek open with one hand and place one film flat against the cheek with your other hand. Do not rub the film into the cheek with your finger.
- Place the film directly onto the inside of the cheek. Do not place film on teeth.
- Remove fingers from the cheek.
- **If the film is spit out or blown out immediately, attempt to give another dose using a new film. If you cannot give the dose, call for emergency help.**

Step 3. Allow Film to Dissolve

- **If the film is accidentally swallowed or chewed, there is no need to give a replacement dose.**
- LIBERVANT will stick to the inside of the cheek and begin to dissolve.
- The mouth can be closed or remain open while waiting.
- Saliva may be swallowed normally as the film dissolves.



What to do after LIBERVANT has been taken:

- Note the time LIBERVANT was taken and changes in the resting breath rate.

- Your child’s healthcare provider may prescribe a second dose of LIBERVANT. If a second dose is needed, it may be given at least 4 hours after the first dose of LIBERVANT film is given. Repeat Steps 1 through 3.
- **Do not** give a second dose if:
 - you are concerned about your child’s breathing,
 - an emergency rescue treatment with breathing help is needed,
 - or there is more sleepiness than normal.
- **Call for emergency medical help** if any of the following occur:
 - there is an increase in seizure frequency that does not stop after using LIBERVANT as instructed by your child’s healthcare provider
 - seizure behavior is different from other episodes
 - the frequency or severity of the seizure is alarming
 - either skin color or breathing is alarming

Disposing of LIBERVANT

- Throw away (dispose of) empty foil pouch with the regular trash. Any films that were spit out or not used after opening should be flushed down the toilet or placed in the sink and rinsed with water until film is no longer visible.

For more information about LIBERVANT, go to www.aquestive.com or call 1-877-394-5045.

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Warren, NJ 07059

This Instructions for Use has been approved by the U.S. Food and Drug Administration

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