



For the acute treatment of agitation
related to **bipolar disorder**,

IGALMI is proven to help reduce agitation

IGALMI is the only FDA-approved sublingual* film
that can start to reduce agitation related to
bipolar disorder I or II in as early as 20 minutes.

*Placed under the tongue or behind the lower lip.
All patients and healthcare providers are actor portrayals.

Limitations of Use: The safety and effectiveness of IGALMI have not been established beyond 24 hours from the first dose.

What is IGALMI?

IGALMI® (dexmedetomidine) sublingual film is a prescription medicine that is placed under your tongue or behind your lower lip and is used for the acute treatment of agitation associated with bipolar disorder I or II in adults. The safety and effectiveness of IGALMI has not been studied beyond 24 hours from the first dose. It is not known if IGALMI is safe and effective in children.

IMPORTANT SAFETY INFORMATION

IGALMI is taken under the supervision of a healthcare provider who will monitor your vital signs (like blood pressure and heart rate) and alertness after you take IGALMI to prevent you from falling or fainting.

Please see additional Important Safety Information throughout and on page 8.



Igalmi[®]
(dexmedetomidine)
sublingual film • 120 mcg, 180 mcg

IGALMI is the first and only FDA-approved sublingual film used in the acute treatment of agitation related to bipolar disorder in adults



It's common to feel like you don't have a part in your care during an agitation episode. Unlike other treatments for agitation in the acute setting, IGALMI is self-administered under the supervision of a healthcare provider.

Your healthcare provider will stay with you while you take IGALMI and monitor you afterward for side effects.

The content in this brochure is for educational purposes only. It is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Always seek the advice of your healthcare provider with any questions you may have regarding agitation associated with bipolar disorder.

IMPORTANT SAFETY INFORMATION (continued)

IGALMI can cause serious side effects, including:

- **Decreased blood pressure, low blood pressure upon standing, and slower than normal heart rate**, which may be more likely in patients with low blood volume, diabetes, chronic high blood pressure, and older patients. IGALMI is taken under the supervision of a healthcare provider who will monitor your vital signs (like blood pressure and heart rate) and alertness after you take IGALMI to prevent you from falling or fainting. Make sure you are adequately hydrated and sit or lie down after taking IGALMI. Tell your healthcare provider if you feel dizzy, lightheaded, or faint.

Please see additional Important Safety Information on page 8.

Agitation looks different for each person



It's estimated that **over 1 million adults living with bipolar disorder** in the US may experience agitation.



Agitation due to bipolar disorder has a **range of symptoms**. These symptoms can be mild, moderate, or severe.



Timing is important. The earlier you (or a loved one) recognize the symptoms, **the better the chance you may have to manage them before they escalate**. Speak up and let your healthcare provider know what you're feeling so you may receive help as quickly as possible.

Recognize the symptoms of an agitation episode

Here are some common symptoms. Which ones do you experience?

- | | | |
|---|---|--|
| <input type="checkbox"/> Restlessness | <input type="checkbox"/> Irritability | <input type="checkbox"/> Hostility |
| <input type="checkbox"/> Uneasiness | <input type="checkbox"/> Fidgeting | <input type="checkbox"/> Being uncooperative |
| <input type="checkbox"/> Nervousness | <input type="checkbox"/> Feeling wound up | <input type="checkbox"/> Aggressiveness |
| <input type="checkbox"/> Feeling tense | <input type="checkbox"/> Feeling overexcited | <input type="checkbox"/> Violence |
| <input type="checkbox"/> Inability to sit still | <input type="checkbox"/> Feeling short-tempered | |

These are not all of the symptoms. Talk to your healthcare provider about the specific symptoms you experience, along with the treatment options you would prefer.



Feel less agitated with IGALMI



IGALMI is a mint-flavored sublingual film. It's placed in the mouth (either under the tongue or behind the lower lip), allowing the medicine to be directly absorbed into the bloodstream.

Some things to consider when talking to a healthcare provider about IGALMI:



It is given at a **medical facility**



It is **not an injection**



It is **self administered**



It is a sublingual film that **dissolves inside your mouth**



It is taken under the supervision of a healthcare provider who **will monitor you for any possible side effects**



The medicine is **absorbed directly** through your mouth into your bloodstream

Ask your healthcare provider if IGALMI, the mint-flavored film to reduce agitation, may be right for you.

IMPORTANT SAFETY INFORMATION (continued)

IGALMI can cause serious side effects, including:

- **Heart rhythm changes (QT interval prolongation).** You should not take IGALMI if you have an abnormal heart rhythm, a history of an irregular heartbeat, slow heart rate, low potassium, low magnesium, and if you are taking other drugs that affect your heart rhythm. Taking IGALMI if you have a history of abnormal heart rhythm can increase the risk of torsades de pointes and sudden death. Tell your healthcare provider immediately if you feel faint or have heart palpitations.

Please see additional Important Safety Information on page 8.

Proven effective in a clinical study

How it was studied:

The IGALMI clinical study included 378 people with bipolar disorder I or II.

The main goal of the study was to measure the reduction of symptoms of agitation using the Positive and Negative Syndrome Scale-Excited Component (PEC). PEC rated levels of:

EXCITEMENT | UNCOOPERATIVENESS | TENSION | POOR IMPULSE CONTROL | HOSTILITY

What we learned:

IGALMI significantly reduced agitation symptoms, achieving the main goal of the study.



IGALMI also began reducing agitation symptoms in **as early as 20 minutes***



IGALMI also improved agitation in nearly **4 out of 5 people within 2 hours†**



*When compared to placebo, the decrease in agitation with IGALMI was statistically significant beginning at 20 minutes after treatment with both 120 mcg and 180 mcg doses. This was a key secondary goal of the study.

†90.5% of patients treated with IGALMI 180 mcg and 77% of patients treated with IGALMI 120 mcg experienced at least a 40% reduction in agitation as measured by their total PEC score (vs 46% of patients who also experienced at least a 40% reduction on placebo). This was another goal of the study.

IMPORTANT SAFETY INFORMATION (continued)

IGALMI can cause serious side effects, including:

- **Sleepiness/drowsiness.** Do not do activities requiring mental alertness, such as driving or operating hazardous machinery, for at least 8 hours after taking IGALMI.

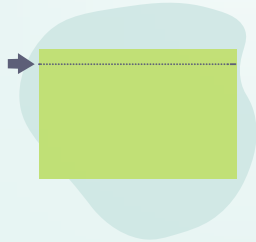
Please see additional Important Safety Information on page 8.

Self administered with the supervision of a healthcare provider

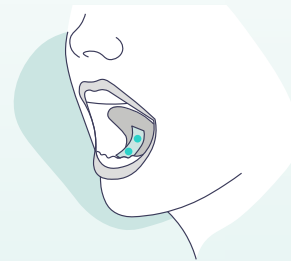
Your healthcare provider will give you IGALMI and help direct you on proper placement in your mouth when you're ready.

How to take IGALMI

STEP 1 IGALMI comes in a small, sealed pouch that is opened by the healthcare provider and given to you.



STEP 2 You will position the film in your mouth, either under your tongue or behind your lower lip. The film is designed to stick in place. Do not chew or swallow the film.

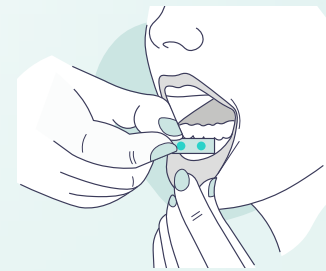


UNDER TONGUE



wait 15 minutes
to eat or drink

OR



BEHIND LOWER LIP



wait 1 hour
to eat or drink

Make sure you are adequately hydrated and sit or lie down after taking IGALMI. Tell your healthcare provider if you feel dizzy, lightheaded, or faint.

After taking IGALMI, your healthcare provider will monitor your vital signs and alertness, as well as check for any possible side effects. They may ask you to remain seated or lying down to reduce the risk of falling in case you feel dizzy.

IMPORTANT SAFETY INFORMATION (continued)

IGALMI can cause serious side effects, including:

- **Decreased blood pressure, low blood pressure upon standing, and slower than normal heart rate**, which may be more likely in patients with low blood volume, diabetes, chronic high blood pressure, and older patients. Make sure you are adequately hydrated and sit or lie down after taking IGALMI. Tell your healthcare provider if you feel dizzy, lightheaded, or faint.

Please see additional Important Safety Information on page 8.

Safety considerations with IGALMI

There are side effects that you may experience when taking IGALMI.

The most common side effects that occurred in 5% or more of people taking IGALMI in clinical studies included:

- Mild to moderate sleepiness/drowsiness
- Prickling or tingling sensation or numbness of the mouth
- Dizziness
- Low blood pressure
- Low blood pressure upon standing
- Dry mouth

The majority of side effects were mild to moderate in severity. These are not all the possible side effects of IGALMI. Please review the Important Safety Information on page 8 and speak with your healthcare provider for medical advice about side effects.



IGALMI is not a controlled substance.

Physical dependence, withdrawal symptoms (eg, nausea, vomiting, agitation), and decreased response to IGALMI may occur if IGALMI is used longer than 24 hours.



Important Safety Information



IGALMI can cause serious side effects, including:

- **Decreased blood pressure, low blood pressure upon standing, and slower than normal heart rate**, which may be more likely in patients with low blood volume, diabetes, chronic high blood pressure, and older patients. IGALMI is taken under the supervision of a healthcare provider who will monitor your vital signs (like blood pressure and heart rate) and alertness after you take IGALMI to prevent you from falling or fainting. Make sure you are adequately hydrated and sit or lie down after taking IGALMI. Tell your healthcare provider if you feel dizzy, lightheaded, or faint.
- **Heart rhythm changes (QT interval prolongation)**. You should not take IGALMI if you have an abnormal heart rhythm, a history of an irregular heartbeat, slow heart rate, low potassium, low magnesium, and if you are taking other drugs that affect your heart rhythm. Taking IGALMI if you have a history of abnormal heart rhythm can increase the risk of torsades de pointes and sudden death. Tell your healthcare provider immediately if you feel faint or have heart palpitations.
- **Sleepiness/drowsiness**. Do not do activities requiring mental alertness, such as driving or operating hazardous machinery, for at least 8 hours after taking IGALMI.
- **Withdrawal reactions, tolerance, and decreased response/efficacy**. IGALMI was not studied for longer than 24 hours after the first dose. Physical dependence, withdrawal symptoms (e.g., nausea, vomiting, agitation), and decreased response to IGALMI may occur if IGALMI is used longer than 24 hours.

The most common side effects of IGALMI in clinical studies were sleepiness or drowsiness, a prickling or tingling sensation or numbness of the mouth, dizziness, dry mouth, low blood pressure, and low blood pressure upon standing.

These are not all the possible side effects of IGALMI. Speak with your healthcare provider for medical advice about side effects.

Tell your healthcare provider about your medical history, including if you suffer from any known heart problems, low potassium, low magnesium, low blood pressure, low heart rate, diabetes, high blood pressure, history of fainting, or liver impairment. Tell your healthcare provider if you are pregnant or breastfeeding or take any medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take any drugs that lower your blood pressure, change your heart rate, or take anesthetics, sedatives, hypnotics, and opioids.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You can also contact BioXcel Therapeutics, Inc. at 1-833-201-1088 or medinfo@bioxceltherapeutics.com.

Please see full [Prescribing Information](#).

Find out if IGALMI is right for you

The next time you're at a medical facility, do not hesitate to speak up and ask your healthcare provider if IGALMI, the mint-flavored film, can help.



Visit IGALMI.com to learn more.