

• IGALMI™

- Sublingual/buccal Film: 120 mcg, 180 mcg
(Half Film: 60 mcg, 90 mcg)

If you or someone you know is in crisis, please call 911 and/or the toll-free National Suicide Prevention Lifeline at 800-273-TALK (8255) to speak with a trained crisis counselor 24/7. A help line and other resources are also available through the National Alliance on Mental Illness at nami.org.



What is dexmedetomidine and what does it treat?

Dexmedetomidine is an alpha-2 adrenergic receptor agonist. It is approved for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder.

Symptoms of agitation may be mild, moderate or severe and recommended doses differ based on symptom severity, liver function, and age.

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

Do not drive a car or operate machinery for at least 8 hours after receiving dexmedetomidine.

Dexmedetomidine is administered under the supervision of a health care provider. Because dexmedetomidine can lower your blood pressure, vital signs and alertness are monitored frequently to prevent falls and fainting.

Dexmedetomidine may be administered for a maximum of up to 3 times at least two hours apart and has not been studied in time periods lasting more than 24 hours.

Are there specific concerns about dexmedetomidine and pregnancy?

If you are planning on becoming pregnant, notify your health care provider to best manage your medications. People living with mental health disorders who wish to become pregnant face important decisions. It is important to discuss this with your doctor and caregivers.

Regarding breastfeeding, caution is advised since dexmedetomidine does pass into breast milk.

What should I discuss with my health care provider before taking dexmedetomidine?

- Any medical problems you have, such as heart rhythm problems, or history of a heart attack
- All other medications you are currently taking (including over the counter products, herbal and nutritional supplements) and any medication allergies
- If you are pregnant, plan to become pregnant, or are breastfeeding
- If you smoke, drink alcohol, or use illegal drugs

All FDA warnings are at the end of this fact sheet. Please consult them before taking this medication.

How should I take dexmedetomidine?

Dexmedetomidine is administered under the supervision of a health care provider. The film is placed either under the tongue or behind the lower lip where it then dissolves. Do not chew or swallow the film. If placed under the tongue, do not eat or drink for 15 minutes. If placed behind the lower lip, do not eat or drink for one hour.

What should I avoid while taking dexmedetomidine?

Avoid standing up quickly and remain seated or lying down after receiving the medication.

What happens if I overdose with dexmedetomidine?

As the medication is administered under the supervision of a health care provider, overdoses are unlikely to occur.

However, if an overdose occurs, call your doctor or 911. You may need urgent medical care. You may also contact the poison control center at 1-800-222-1222.

A specific treatment to reverse the effects of dexmedetomidine does not exist.

What are the possible side effects of dexmedetomidine?

Common side effects

Drowsiness/sedation, dizziness, lowered blood pressure, dry mouth or tingling/numbness of the mouth

Rare/serious side effects

A slowed heart rate and drop in blood pressure when sitting up may occur; caution in those with advanced heart block, heart rhythm abnormalities or history of fainting due to low blood pressure. Drinking water and lying down until vital signs are within range is advised.

Dexmedetomidine may cause an arrhythmia (irregular heartbeat). To minimize this risk, other medications known to increase heart rhythms (called a prolonged QT interval) should be avoided at time of administration of dexmedetomidine. The medication should be avoided in those with a history of slow heart rate, low potassium, or low magnesium. Your doctor may order an EKG to monitor for irregular heartbeat.

Symptoms of withdrawal have been observed with another dexmedetomidine product administered through the veins for more than 7 days. The most common symptoms of withdrawal were nausea, vomiting, and agitation. Dexmedetomidine film (IGALMI™) was not studied for longer than 24 hours after the first dose and there may be a risk of dependence and withdrawal syndrome if dexmedetomidine is used in a manner other than intended.

What other medications may interact with dexmedetomidine?

Drugs that may increase heart rhythms (prolong the QT interval) should be avoided.

Sedating or sleep-inducing drugs and pain medications containing opioids may increase the effects of dexmedetomidine and the dose may need to be adjusted.

How long does it take for dexmedetomidine to work?

Decrease in agitation may be seen within 20 to 30 minutes depending on the dose. If agitation persists, another dose may be administered 2 hours later and repeated one more time 2 hours after the previous dose.

Important Disclosure: This information is being provided as a community outreach effort of the American Association of Psychiatric Pharmacists. This information is for educational and informational purposes only and is not medical advice. This information contains a summary of important points and is not an exhaustive review of information about the medication. Always seek the advice of a physician or other qualified medical professional with any questions you may have regarding medications or medical conditions. Never delay seeking professional medical advice or disregard medical professional advice as a result of any information provided herein. The American Association of Psychiatric Pharmacists disclaims any and all liability alleged as a result of the information provided herein.