

- **Saphris®**
 - Orally disintegrating sublingual tablets: 2.5 mg, 5 mg, 10 mg

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 asenapine and what does it treat?

Asenapine is a medication that works in the brain to treat schizophrenia. It is also known as a second generation antipsychotic (SGA) or atypical antipsychotic. Asenapine rebalances dopamine and serotonin to improve thinking, mood, and behavior.

Symptoms of schizophrenia include:

- Hallucinations - imagined voices or images that seem real
- Delusions - beliefs that are not true (e.g., other people are reading your thoughts)
- Disorganized thinking or trouble organizing your thoughts and making sense
- Little desire to be around other people
- Trouble speaking clearly
- Lack of motivation

Asenapine may help some or all of these symptoms.

Asenapine is also FDA approved for the following indications:

- Acute treatment of manic or mixed episodes of bipolar I disorder in adults (alone or in combination with lithium or valproic acid)
- Acute treatment of manic episodes of bipolar I disorder in pediatrics (10 – 17 years old)

This medication sheet will focus primarily on schizophrenia. You can find more information about bipolar disorders at [here](#).

Asenapine may also be helpful when prescribed “off-label” for psychosis or agitation associated with dementia. “Off-label” means that it has not been approved by the Food and Drug Administration for this condition. Your mental health provider should justify his or her thinking in recommending an “off-label” treatment. They should be clear about the limits of the research around that medication and if there are any other options.

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

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

Schizophrenia requires long-term treatment. Do not stop taking asenapine, even when you feel better.

Only your healthcare provider can determine the length of asenapine treatment that is right for you.

Missing doses of asenapine may increase your risk for a relapse in your symptoms.

Do not stop taking asenapine or change your dose without talking to with your healthcare provider first.

For asenapine to work properly, it should be taken every day as ordered by your healthcare provider.

Are there specific concerns about asenapine and pregnancy?

If you are planning on becoming pregnant, notify your healthcare provider to best manage your medications. People living with schizophrenia who wish to become pregnant face important decisions. This is a complex decision since untreated schizophrenia has risks to the fetus, as well as the mother. It is important to discuss the risks and benefits of treatment with your doctor and caregivers.

Breastfeeding is not recommended in women who are taking asenapine. It is not known if asenapine passes into breast milk.

What should I discuss with my healthcare provider before taking asenapine?

- Symptoms of your condition that bother you the most
- If you have thoughts of suicide or harming yourself
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- If you ever had muscle stiffness, shaking, tardive dyskinesia, neuroleptic malignant syndrome, or weight gain caused by a medication
- If you experience side effects from your medications, discuss them with your provider. Some side effects may pass with time, but others may require changes in the medication.
- Any psychiatric or medical problems you have, such as heart rhythm problems, long QT syndrome, heart attacks, diabetes, high cholesterol, or seizures
- If you have a family history of diabetes or heart disease
- All other medications you are currently taking (including over the counter products, herbal and nutritional supplements) and any medication allergies you have
- Other non-medication treatment you are receiving, such as talk therapy or substance abuse treatment. Your provider can explain how these different treatments work with the medication.
- If you are pregnant, plan to become pregnant, or are breast-feeding
- If you smoke, drink alcohol, or use illegal drugs

How should I take asenapine?

Asenapine is usually taken 2 times per day. Do not eat or drink for 10 minutes after taking asenapine.

Typically patients begin at a low dose of medicine and the dose is increased slowly over several weeks.

The dose usually ranges from 5 mg to 10 mg. Only your healthcare provider can determine the correct dose for you.

Asenapine orally disintegrating tablets must remain in their original packaging. Open the package with clean dry hands before each dose. Do not try to put tablets in a pillbox if you take the orally disintegrating tablets.

The sublingual tablets will dissolve within seconds when placed under your tongue. It should not be swallowed.

Use a calendar, alarm clock, or cell phone alert to help you remember to take your medication. You may also ask a family member or friend to remind you or check in with you to be sure you are taking your medication.

What happens if I miss a dose of asenapine?

If you miss a dose of asenapine, take it as soon as you remember, unless it is closer to the time of your next dose. Discuss this with your healthcare provider. Do not double your next dose or take more than what is prescribed.

What should I avoid while taking asenapine?

Avoid drinking alcohol or using illegal drugs while you are taking asenapine. They may decrease the benefits (e.g. worsen your confusion) and increase adverse effects (e.g. sedation) of the medication.

What happens if I overdose with asenapine?

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 asenapine does not exist.

What are the possible side effects of asenapine?

Common side effects

- Temporary numbness of the mouth and tongue
- Feeling drowsy or dizzy

Rare/Serious side effects

Asenapine may increase the blood levels of a hormone called prolactin. Side effects of increased prolactin levels include females losing their period, production of breast milk and males losing their sex drive or possibly experiencing erectile problems. Long term (months or years) of elevated prolactin can lead to osteoporosis, or increased risk of bone fractures.

Some people may develop muscle related side effects while taking asenapine. The technical terms for these are “extrapyramidal effects” (EPS) and “tardive dyskinesia” (TD). Symptoms of EPS include restlessness, tremor, and stiffness. TD symptoms include slow or jerky movements that one cannot control, often starting in the mouth with tongue rolling or chewing movements.

Second generation antipsychotics (SGAs) increase the risk of weight gain, high blood sugar, and high cholesterol. This is also known as metabolic syndrome. Your healthcare provider may ask you for a blood sample to check your cholesterol, blood sugar, and hemoglobin A1c (a measure of blood sugar over time) while you take this medication.

- Information on healthy eating and adding exercise to decrease your chances of developing metabolic syndrome may be found at the following sites:
 - <http://www.helpguide.org/articles/healthy-eating/healthy-eating.htm>
 - <http://www.helpguide.org/home-pages/exercise-fitness.htm>

SGAs have been linked with higher risk of death, strokes, and transient ischemic attacks (TIAs) in elderly people with behavior problems due to dementia.

All antipsychotics have been associated with the risk of sudden cardiac death due to an arrhythmia (irregular heart beat). To minimize this risk, antipsychotic medications should be used in the smallest effective dose when the benefits outweigh the risks. Your doctor may order an EKG to monitor for irregular heartbeat.

Neuroleptic malignant syndrome is a rare, life threatening adverse effect of antipsychotics which occurs in <1% of patients. Symptoms include confusion, fever, extreme muscle stiffness, and sweating. If any of these symptoms occur, contact your healthcare provider immediately.

All antipsychotics can cause sedation, dizziness, or orthostatic hypotension (a drop in blood pressure when standing up from sitting or lying down). These side effects may lead to falls which could cause bone fractures or other injuries. This risk is higher for people with conditions or other medications that could worsen these effects. If falls or any of these symptoms occur, contact your healthcare provider.

Are there any risks for taking asenapine for long periods of time?

Tardive dyskinesia (TD) is a side effect that develops with prolonged use of antipsychotics. Medications such as asenapine have been shown to have a lower risk of TD compared to older antipsychotics, such as Haldol® (haloperidol). If you develop symptoms of TD, such as grimacing, sucking, and smacking of lips, or other movements that you cannot control, contact your healthcare provider immediately. All patients taking either first or second generation antipsychotics should have an Abnormal Involuntary Movement Scale (AIMS) completed regularly by their healthcare provider to monitor for TD.

Second generation antipsychotics (SGAs) increase the risk of diabetes, weight gain, high cholesterol, and high triglycerides. (See “Serious Side Effects” section for monitoring recommendations.)

What other medications may interact with asenapine?

Asenapine may block the effects of agents used to treat Parkinson’s disease such as levodopa/carbidopa (Sinemet®), bromocriptine, pramipexole (Mirapex®), ropinirole (Requip®), and others.

The following medications may increase the risk of heart problems when used with asenapine:

- Antipsychotics, including chlorpromazine (Thorazine®), thioridazine (Mellaril®), iloperidone (Fanapt®), paliperidone (Invega®), quetiapine (Seroquel®), and ziprasidone (Geodon®).
- Antiarrhythmics (heart rhythm medications), including procainamide, quinidine, amiodarone (Cordarone®), dronedarone (Multaq®), and sotalol (Betapace®).

The following medications may **increase** the levels and effects of asenapine:

- Fluvoxamine (Luvox®), paroxetine (Paxil®), and ciprofloxacin (Cipro®).

How long does it take for asenapine to work?

It is very important to tell your doctor how you feel things are going during the first few weeks after you start taking asenapine. It will probably take several weeks to see big enough changes in your symptoms to decide if asenapine is the right medication for you.

Antipsychotic treatment is generally needed lifelong for persons with schizophrenia. Your doctor can best discuss the duration of treatment you need based on your symptoms and illness.

- Hallucinations, disorganized thinking, and delusions may improve in the first 1-2 weeks
- Sometimes these symptoms do not completely go away
- Motivation and desire to be around other people can take at least 1-2 weeks to improve
- Symptoms continue to get better the longer you take asenapine
- It may take 2-3 months before you get the full benefit of asenapine

Summary of Black Box Warnings

Increased Mortality in Elderly Patients with Dementia Related Psychosis

- Both first generation (typical) and second generation (atypical) antipsychotics are associated with an increased risk of mortality in elderly patients when used for dementia related psychosis.
- Although there were multiple causes of death in studies, most deaths appeared to be due to cardiovascular causes (e.g. sudden cardiac death) or infection (e.g. pneumonia).
- Antipsychotics are not indicated for the treatment of dementia-related psychosis.

Important Disclosure: This information is being provided as a community outreach effort of the College of Psychiatric and Neurologic 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 College of Psychiatric and Neurologic Pharmacists disclaims any and all liability alleged as a result of the information provided herein.