



- **Paliperidone**
 - Extended-release oral tablet: 1.5 mg, 3 mg, 6 mg, 9 mg
- **Invega®**
 - Extended-release oral tablet: 1.5 mg, 3 mg, 6 mg, 9 mg
- **Invega Sustenna®**
 - Extended-release intramuscular suspension: 39 mg, 78 mg, 117 mg, 156 mg, 234 mg
- **Invega Trinza®**
 - Extended-release intramuscular suspension: 273 mg, 410 mg, 546 mg, 819 mg
- **Invega Hafyera™**
 - Extended-release intramuscular suspension: 1,092 mg, 1,560 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 paliperidone and what does it treat?

Paliperidone is a medication that works in the brain to treat schizophrenia and schizoaffective disorder. It is also known as a second generation antipsychotic (SGA) or atypical antipsychotic. Paliperidone 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

Schizoaffective disorder is an illness that includes symptoms of schizophrenia as well as abnormal moods (elevated and/or depressed mood).

Mood symptoms include:

- Depressed mood – feeling sad, empty, or tearful
- Feeling worthless, guilty, hopeless, or helpless
- Loss of interest or pleasure in normal activities
- Sleep and eat more or less than usual (for most people it is less)
- Low energy, trouble concentrating, or thoughts of death (suicidal thinking)
- Psychomotor agitation (‘nervous energy’)
- Psychomotor retardation (feeling like you are moving in slow motion)
- Feeling irritable or ‘high’
- Having increased self esteem
- Feeling like you don’t need to sleep
- Feeling the need to continue to talk
- Feeling like your thoughts are too quick (racing thoughts)
- Feeling distracted
- Getting involved in activities that are risky or could have bad consequences (e.g., excessive spending)

Paliperidone may help some or all of these symptoms.

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

Paliperidone may also be helpful when prescribed “off-label” for manic or mixed episodes of bipolar disorder. “Off-label” means that it hasn’t 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 paliperidone?

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

With input from you, your health care provider will assess how long you will need to take the medication.

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

Do not stop taking paliperidone or change your dose without talking with your health care provider first.

For paliperidone to work properly, it should be taken every day as ordered by your health care provider.

Are there specific concerns about paliperidone and pregnancy?

If you are planning on becoming pregnant, notify your health care 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.

Antipsychotic use during the third trimester of pregnancy has a risk for abnormal muscle movements (extrapyramidal symptoms [EPS]) and/or withdrawal symptoms in newborns following delivery. Symptoms in the newborn may include agitation, feeding disorder, hypertonia, hypotonia, respiratory distress, somnolence, and tremor; these effects may be self-limiting or require hospitalization.

Caution is advised with breastfeeding since paliperidone does pass into breast milk.

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

- 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 breastfeeding
- If you smoke, drink alcohol, or use illegal drugs

How should I take paliperidone?

Paliperidone tablets are usually taken 1 time per day with or without food.

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

The dose of the tablets usually ranges from 3 mg to 12 mg. The dose of the Sustenna brand of long-acting paliperidone injection formulation usually ranges from 78 mg to 234 mg every month. The dose of the Trinza brand long-acting paliperidone injection formulation ranges from 273mg to 819mg every 3 months. Only your health care provider can determine the correct dose for you.

The tablets should be swallowed whole. They should not be chewed, crushed, or broken.

Use a calendar, pillbox, 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.

The Sustenna brand of long-acting injection paliperidone is administered twice in the first 8 days of treatment, then every 4 weeks. Your health care provider will administer these injections.

The Trinza brand of long-acting injection paliperidone is administered every 3 months. Your health care provider will administer these injections.

The Hafyera brand of long-acting injection paliperidone is administered every 6 months. Your health care provider will administer these injections.

What happens if I miss a dose of paliperidone?

If you miss a dose of oral paliperidone, take it as soon as you remember, unless it is closer to the time of your next dose. Do not double your next dose or take more than what is prescribed. If you miss an injection, call your doctor or pharmacist right away. Discuss this with your health care provider.

What should I avoid while taking paliperidone?

Avoid drinking alcohol or using illegal drugs while you are taking paliperidone. 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 paliperidone?

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 paliperidone does not exist.

What are the possible side effects of paliperidone?

Common side effects

Rapid heartbeat, drowsiness, extrapyramidal symptoms, restlessness, headache, increased prolactin, weight gain, cholesterol abnormalities, increased glucose, vomiting, tremor, anxiety

Injections may cause localized reactions such as redness or swelling at the site of injection

Rare/serious side effects

Paliperidone 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) elevated prolactin levels can lead to osteoporosis, or increased risk of bone fractures.

Some people may develop muscle related side effects while taking paliperidone. The technical terms for these are “extrapyramidal symptoms” (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.

Temperature regulation: Impaired core body temperature regulation may occur; caution with strenuous exercise, heat exposure, and dehydration.

Second generation antipsychotics (SGAs) increase the risk of weight gain, high blood sugar, and high cholesterol. This is also known as metabolic syndrome. Your health care 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 health care 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 health care provider.

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

Tardive dyskinesia (TD) is a side effect that develops with prolonged use of antipsychotics. Medications such as paliperidone 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 health care provider immediately. All patients taking either first or second generation antipsychotics should have an Abnormal Involuntary Movement Scale (AIMS) completed regularly by their health care 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 paliperidone?

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

Paliperidone may lower your blood pressure. Medications used to lower blood pressure may increase this effect and increase your risk of falling. Propranolol (Inderal®) is an example of this type of medication.

The following medications may increase the risk of heart problems when used with paliperidone.

- Antipsychotics including chlorpromazine (Thorazine®), thioridazine (Mellaril®), iloperidone (Fanapt®), asenapine (Saphris®), 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 paliperidone: divalproex sodium (Depakote®).

The following medications may decrease the levels and effects of paliperidone: carbamazepine (Tegretol®, Equatro®), rifampin, St. John’s Wort.

How long does it take for paliperidone 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 paliperidone. It will probably take several weeks to see big enough changes in your symptoms to decide if paliperidone 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 paliperidone
- It may take 2-3 months before you get the full benefit of paliperidone

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 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.