

Haldol (haloperidol)

FDA ALERT [9/2007]: This Alert highlights revisions to the labeling for haloperidol (marketed as Haldol, Haldol Decanoate and Haldol Lactate). The updated labeling includes WARNINGS stating that Torsades de Pointes and QT prolongation have been observed in patients receiving haloperidol, especially when the drug is administered intravenously or in higher doses than recommended. Haloperidol is not approved for intravenous use.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

Brand and Generic Names:

Ortho-McNeil manufactures and markets haloperidol under the brand name Haldol®. Generic forms of haloperidol are marketed by many different manufacturers.

- Haldol® and haloperidol (generic)
 - Tablets: 0.5 mg, 1 mg, 2 mg, 5 mg, 10 mg, 20 mg
 - Liquid: Oral concentrate as haloperidol lactate 2 mg/mL
 - Injection (short-acting): haloperidol lactate 5 mg/mL
- Haldol® decanoate for injection (long-acting) 50 mg/mL and 100 mg/mL
- Generic name = haloperidol (pronounced hal-oh-**per**-i-dawl)

What is Haldol® and what does it treat?

Haloperidol is an antipsychotic medication used to treat schizophrenia and other psychotic disorders. Haloperidol can improve symptoms of these disorders such as:

hallucinations, delusions, and disorganized thinking. It is also used for tics and vocal utterances of Tourette's disorder and the management of severe behavioral problems in children.

While not approved by the FDA for other uses, haloperidol may be used alone or with other medications to treat other symptoms such as agitation or other behavior problems in older persons with memory loss or people with developmental disabilities.

What is the most important information I should know about Haldol®?

Relapse is very common in schizophrenia and the most frequent cause is that patients stop taking their medication. Even when medication is taken exactly as prescribed, relapse may still occur for some people. Therefore it is recommended that you take your medication exactly as prescribed by your health care provider as this has been shown to delay relapse.

- Schizophrenia requires long-term treatment. Only your healthcare provider can determine the length of haloperidol treatment that is right for you.
- Do not stop taking haloperidol or change your dose without first talking with your healthcare provider.
- Some people may develop side effects on haloperidol such as restlessness, tremor, and stiffness. There are medicines that can be taken to lessen or eliminate these side effects. If you develop these symptoms, call your healthcare provider immediately.
- Haloperidol may cause tardive dyskinesia (TD), a potentially permanent side effect of antipsychotic medications. TD is characterized by movements you may be unable to control such as grimacing, smacking of lips, and spasms of the extremities. Sometimes you may not notice that you are doing these movements. TD usually begins after several months of treatment and may be irreversible. However, if TD is caught early, it may be reversible. If you develop these symptoms, call your healthcare provider immediately.
- Haloperidol should be taken at the same time every day, or if you receive an injection, it is important that you return to clinic to receive it every 4 weeks, or as determined by your healthcare provider.
- If you are receiving haloperidol decanoate long-acting injection, your healthcare provider may continue oral haloperidol for a period of time. You should only stop taking the oral medication once your healthcare provider says to do so. You may still need to take daily medication to help with side effects (e.g. Cogentin®, Benadryl®).

What should I discuss with my healthcare provider before taking Haldol®?

- The symptoms of schizophrenia that are most bothersome to you.
- The medications you have taken in the past for schizophrenia. It would be helpful for your provider to know which medications were effective and which were not.

- If you had any serious side effects to other antipsychotic medications like dystonia, tardive dyskinesia, neuroleptic malignant syndrome, weight gain, or diabetes, tell your healthcare provider.
- If you have ever had seizures.
- All other medications you are currently taking.
- If you smoke cigarettes, use illegal drugs, or drink alcohol.
- About any medication allergies you have.
- If you are pregnant, plan to get pregnant, or are breast feeding.
- Tell your doctor if you have thoughts of suicide.

How should I take Haldol®?

- Oral Haloperidol comes as a tablet or liquid to take by mouth.
- Oral haloperidol is usually taken one to three times daily.
- Haloperidol can be taken with or without food
- Use a calendar or pill box to help you remember to take your medication. Or, have a family member or friend check in with you to make sure you are taking your medication
- The dose that is right for you will be determined by your health care provider. Most patients start at 5 mg to 10 mg per day.
- Most patients will take haloperidol as a long-term maintenance medication (i.e. for years).
- Continue to take haloperidol even if you feel well.
- Do not stop taking haloperidol without talking to your healthcare provider.
- Haloperidol oral liquid comes with a specially marked dropper for measuring the dose. Ask your pharmacist to show you how to use the dropper. Do not allow the liquid to touch your skin or clothing; it can cause skin irritation. Haloperidol liquid may be taken alone or mixed with other liquids. Mix haloperidol liquid in water, Seven-Up, carbonated orange beverage, milk, or V-8, pineapple, apricot, prune, orange, tomato, or grapefruit juice just before taking it. Do not use beverages containing caffeine (coffee, tea, and cola) or apple juice.
- Haloperidol Decanoate long-acting injection will be given at intervals as determined by your healthcare provider, usually every three to four weeks. Your healthcare provider may ask that you continue to take oral haloperidol for a period of time. Once you are on a stable dose of Haloperidol Decanoate long-acting injection, your healthcare provider will ask you to stop taking oral Haldol®. Do not stop taking oral haloperidol until you healthcare provider says to do so.

What happens if I miss a dose?

- If an oral dose of haloperidol is missed, take it as soon as you remember, as long as it is not too close to when your next dose is due. Do not double up on your next dose.
- If a Haloperidol Decanoate long-acting injection dose is missed, call your healthcare provider as soon as you remember to so you can get to the clinic as soon as possible to receive your injection.

What should I avoid while taking Haldol®?

- Please check with your healthcare provider before taking any other prescription, over-the-counter, or herbal/nutritional supplements.
- Smoking cigarettes, using illegal drugs, or drinking alcohol.
- Some people get drowsy while taking Haldol®; avoid driving a car or operating heavy machinery until you are sure how the medication will affect you.

What happens if I overdose?

- If an overdose occurs, whether intentional or accidental, immediate medical attention is necessary. Call your doctor or emergency medical service (911).
- The following may occur in an overdose: increased heart rate, low blood pressure, sedation, extrapyramidal symptoms, seizures, irregular heart rhythms. In severe cases, people can develop coma and death is possible.
- It is very important to take haloperidol exactly as prescribed by your healthcare provider.

What are the possible side effects of Haldol®?

Common adverse effects of haloperidol usually include sleepiness, dizziness, rapid heart beat, constipation, excess saliva production and weight gain. Another important adverse effect that occurs commonly is orthostatic hypotension (a lowering of your blood pressure when you are sitting up or standing up). Occasionally this can lead to fainting and falling down, therefore, people taking Haloperidol should be careful when they change positions. These adverse effects are usually mild and usually go away after the first several days of starting treatment or increasing a dose.

Patients receiving haloperidol decanoate long-acting injection may notice some pain at the site of the injection.

Haloperidol has the potential of causing extrapyramidal symptoms (EPS) such as muscle spasms, cramps, or posturing movements common to other antipsychotic medications, and side effects such as restlessness, muscle rigidity, and tremor.

Haloperidol may cause tardive dyskinesia (TD), a potentially permanent side effect of standard antipsychotic medications. TD is characterized by movements you may be

unable to control such as grimacing, sucking/smacking of lips, and spasms of the extremities. Sometimes you may not notice that you are doing these movements. TD usually begins after several months of treatment and may be irreversible. However, if TD is caught early, it may be able to be reversed.

If you experience any of the following symptoms, call your doctor immediately:

- jaw, neck, and back muscle spasms
- slow or difficult speech
- shuffling walk
- persistent fine tremor or inability to sit still
- fever, chills, sore throat, or flu-like symptoms
- difficulty breathing or swallowing
- severe skin rash
- yellowing of the skin or eyes
- irregular heartbeat

Are there any risks for taking this medication for long periods of time?

Long term treatment with antipsychotics has caused tardive dyskinesia (TD) in some patients. Your healthcare provider will regularly monitor for the development of TD. TD is characterized by movements you may be unable to control such as grimacing, sucking/smacking of lips, and spasmodic movements of the extremities. Sometimes you may notice that you are doing these movements. TD usually begins after several months of treatment and may be irreversible.

What other drugs interact with this medication?

- There are many other medications that may interact with Haldol[®]. Any other medication that causes sleepiness or low blood pressure may increase the same side effects of Haloperidol and increase your chances of falling. Talk to your healthcare provider or pharmacist before starting any other medication, including over-the-counter medications, vitamins, dietary supplements, and natural (herbal) products.
- Medications that may increase levels of Haloperidol in your body: ciprofloxacin (Cipro[®]), cimetidine (Tagamet[®]), erythromycin, fluoxetine (Prozac[®]), fluvoxamine (Luvox[®]), isoniazid (INH), mexiletine (Mexitol[®]), paroxetine (Paxil[®]), and azole antifungals (Ketoconazole, Nizoral[®]).
- Medications that may decrease levels of Haloperidol in your body: carbamazepine (Tegretol[®]), lopinavir/ritonavir (Kaletra[®]), ritonavir (Norvir[®]), phenobarbital, phenytoin (Dilantin[®]), rifampin (Rifadin[®]), omeprazole (Prilosec[®]), oxcarbazepine (Trileptal[®]). Cigarette smoking may also decrease the effectiveness of haloperidol.

How long does it take for Haldol® to work?

- A person should try Haloperidol for at least four to six weeks; this is when the maximum effects of the medication are usually seen. However, some symptoms such as hallucinations, anxiety, and paranoia should lessen within a few days to a few weeks.

*Updated by Raymond A. Lorenz, PharmD
(October 2006)*



NAMI wishes to thank the [College of Psychiatric and Neurological Pharmacists](#) for producing this fact sheet.

Reviewed by Dr. Ken Duckworth, NAMI Medical Director

For further information. Please contact the pharmaceutical company listed below.

Ortho-McNeil Pharmaceutical, Inc.	1125 Trenton- Harbourton Road P.O. Box 200 Titusville, NJ 08560-200	800-577- 3788	www.access2wellness.com
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Free or low-cost medications provided by pharmaceutical companies

Some pharmaceutical companies offer medication assistance programs to low-income individuals and families. These programs typically require a doctor's consent and proof of financial status. They may also require that you have either no health insurance, or no prescription drug benefit through your health insurance. Please contact the pharmaceutical company directly for specific eligibility requirements and application information.

Haldol Rx Assistance Program: www.access2wellness.com