

# PATIENT PACKAGE INSERT

## DONEPEZIL HYDROCHLORIDE TABLETS, USP

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- Tablets: 5 mg and 10 mg

Read the Patient Information that comes with donepezil hydrochloride tablets before the patient starts taking them and each time you get a refill. There may be new information. This leaflet does not take the place of talking with the doctor about Alzheimer's disease or treatment for it. If you have questions, ask the doctor or pharmacist.

### What are donepezil hydrochloride tablets?

Donepezil hydrochloride comes as film-coated tablets in dosage strengths of 5 mg and 10 mg.

Donepezil hydrochloride tablets are prescription medicine to treat mild, moderate, and severe Alzheimer's disease. Donepezil hydrochloride tablets can help with mental function and with doing daily tasks. Donepezil hydrochloride tablets do not work the same in all people. Some people may:

- Seem much better
- Get better in small ways or stay the same
- Get worse over time but slower than expected
- Not change and then get worse as expected

Donepezil hydrochloride tablets do not cure Alzheimer's disease. All patients with Alzheimer's disease get worse over time, even if they take donepezil hydrochloride tablets.

Donepezil hydrochloride tablets have not been approved as a treatment for any medical condition in children.

### Who should not take donepezil hydrochloride tablets?

The patient should not take donepezil hydrochloride tablets if allergic to any of the ingredients in donepezil hydrochloride tablets or to medicines that contain piperidines. Ask the patient's doctor if you are not sure. See the end of this leaflet for a list of ingredients in donepezil hydrochloride tablets.

### What should I tell the doctor before the patient takes donepezil hydrochloride tablets?

### Tell the doctor about all the patient's present or past health problems.

Include:

- Any heart problems including problems with irregular, slow, or fast heartbeats
- Asthma or lung problems
- A seizure
- Stomach ulcers
- Difficulty passing urine
- Liver or kidney problems

- Trouble swallowing tablets
- Present pregnancy or plans to become pregnant. It is not known if donepezil hydrochloride tablets can harm an unborn baby.
- Present breast-feeding. It is not known if donepezil hydrochloride passes into breast milk. Donepezil hydrochloride tablets are not for women who are breast-feeding.

**Tell the doctor about all the medicines the patient takes,** including prescription and non-prescription medicines, vitamins, and herbal products. Donepezil hydrochloride tablets and other medicines may affect each other.

Be particularly sure to tell the doctor if the patient takes aspirin or medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). There are many NSAID medicines, both prescription and non-prescription. Ask the doctor or pharmacist if you are not sure if any of the patient's medicines are NSAIDs. Taking NSAIDs and donepezil hydrochloride tablets together may make the patient more likely to get stomach ulcers.

Donepezil hydrochloride tablets taken with certain medicines used for anesthesia may cause side effects. Tell the responsible doctor or dentist that the patient takes donepezil hydrochloride tablets before the patient has:

- surgery
- medical procedures
- dental surgery or procedures.


Know the medicines that the patient takes. Keep a list of all the patient's medicines. Show it to the doctor or pharmacist before the patient starts a new medicine.

### How should the patient take donepezil hydrochloride tablets?

- Give donepezil hydrochloride tablets exactly as prescribed by the doctor. Do not stop donepezil hydrochloride tablets or change the dose yourself. Talk with the doctor first.
- Give donepezil hydrochloride tablets one time each day. Donepezil hydrochloride tablets can be taken with or without food.
- Donepezil hydrochloride tablets 23 mg should be swallowed whole without the tablets being split, crushed, or chewed.
- If you miss giving the patient a dose of donepezil hydrochloride tablets, just wait. Give only the next dose at the usual time. Do not give 2 doses at the same time.
- If donepezil hydrochloride tablets are missed for 7 days or more, talk with the doctor before starting again.
- If the patient takes too much donepezil hydrochloride tablets at one time, call the doctor or poison control center, or go to

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the emergency room right away.

**What are the possible side effects of donepezil hydrochloride tablets?**

**Donepezil hydrochloride tablets may cause the following serious side effects:**

- **slow heartbeat and fainting.** This happens more often in people with heart problems. Call the doctor right away if the patient faints while taking donepezil hydrochloride tablets.
- **more stomach acid.** This raises the chance of ulcers and bleeding. The risk is higher for patients who had ulcers, or take aspirin or other NSAIDs.
- worsening of lung problems in people with asthma or other lung disease.
- seizures.
- difficulty passing urine.

**Call the doctor *right away* if the patient has:**

- fainting.
- heartburn or stomach pain that is new or won't go away.
- nausea or vomiting, blood in the vomit, dark vomit that looks like coffee grounds.
- bowel movements or stools that look like black tar.
- new or worse asthma or breathing problems.
- seizures.
- difficulty passing urine.

**The most common side effects of donepezil hydrochloride tablets are:**

- nausea
- diarrhea
- not sleeping well
- vomiting
- muscle cramps
- feeling tired
- not wanting to eat

**These side effects may get better after the patient takes donepezil hydrochloride tablets for a while. This is not a complete list of side effects with donepezil hydrochloride tablets. For more information, ask the doctor or pharmacist.**

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

**How should donepezil hydrochloride tablets be stored?**

Store at 20°C-25°C (68°F-77°F), excursions permitted to 15°C-30°C (59°F-86°F). [See USP Controlled Room Temperature].

**Keep donepezil hydrochloride tablets and all medicines out of the reach of children.**

**General information about donepezil hydrochloride tablets**

Medicines are sometimes prescribed for conditions that are not mentioned in this Patient Information Leaflet. Do not use donepezil

hydrochloride tablets for a condition for which it was not prescribed. Do not give donepezil hydrochloride tablets to people other than the patient, even if they have the same symptoms as the patient, as they may harm them.

This leaflet summarizes the most important information about donepezil hydrochloride tablets. If you would like more information talk with the patient's doctor. You can ask your pharmacist or doctor for information about donepezil hydrochloride tablets that is written for health professionals.

For more information call toll free 1-800-313-4623.

**What are the ingredients in donepezil hydrochloride tablets?**

**Active ingredient:** donepezil hydrochloride USP

**Inactive ingredients:** corn starch, lactose monohydrate, low substituted hydroxypropyl cellulose, magnesium stearate and microcrystalline cellulose. The film coating contains hypromellose, polyethylene glycol, talc and titanium dioxide.

**Rx Only**

**Manufactured by:**

Jubilant Generics Limited  
Roorkee-247661, India

**Marketed by:**

Jubilant Cadista Pharmaceuticals Inc.  
Salisbury, MD-21801, USA


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