

Donepezil Hydrochloride (doe-NEP-e-zil HYE-droe-KLOR-ide) Tablets, USP

- Tablets: 5 mg and 10 mg

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

What is donepezil hydrochloride?

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

Donepezil hydrochloride is a prescription medicine to treat mild, moderate, and severe Alzheimer's disease. Donepezil hydrochloride can help with mental function and with doing daily tasks. Donepezil hydrochloride does 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 does not cure Alzheimer's disease. All patients with Alzheimer's disease get worse over time, even if they take donepezil hydrochloride.

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

Who should not take donepezil hydrochloride?

Do not take donepezil hydrochloride if you are allergic to any of the ingredients in donepezil hydrochloride or to medicines that contain piperidines. Ask your doctor if you are not sure. See the end of this leaflet for a list of ingredients in donepezil hydrochloride.

What should I tell my doctor before taking donepezil hydrochloride?

Tell the doctor about all of your present or past health problems and conditions. 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 can harm an unborn baby.
- Present breast-feeding. It is not known if donepezil hydrochloride passes into breast milk. Talk to your doctor about the best way to feed your baby if you take donepezil hydrochloride.

Tell the doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal products. Donepezil hydrochloride and other medicines may affect each other.

Be particularly sure to tell the doctor if you take 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 your medicines are NSAIDs. Taking NSAIDs and donepezil hydrochloride together may make you more likely to get stomach ulcers.

Donepezil hydrochloride taken with certain medicines used for anesthesia may cause side effects. Tell the responsible doctor or dentist that you take donepezil hydrochloride before you have:

- surgery
- medical procedures
- dental surgery or procedures.

Know the medicines that you take. Keep a list of all yours medicines. Show it to your doctor or pharmacist before you start a new medicine.

How should you take donepezil hydrochloride?

- Take donepezil hydrochloride exactly as prescribed by the doctor. Do not stop donepezil hydrochloride or change the dose yourself. Talk with your doctor first.
- Take donepezil hydrochloride one time each day. Donepezil hydrochloride can be taken with or without food.
- If you miss a dose of donepezil hydrochloride, just wait. Take only the next dose at the usual time. Do not take 2 doses at the same time.
- If donepezil hydrochloride is missed for 7 days or more, talk with your doctor before starting again.
- If you take too much donepezil hydrochloride at one time, call your doctor or poison control center, or go to the emergency room right away.

What are the possible side effects of donepezil hydrochloride?

Donepezil hydrochloride may cause the following serious side effects:

- slow heartbeat and fainting. This happens more often in people with heart problems. Call your doctor right away if you feel faint or lightheaded while taking donepezil hydrochloride.
- more stomach acid. This raises the chance of ulcers and bleeding, especially when taking donepezil hydrochloride 23 mg. The risk is higher for people who have 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 you have:

- 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 are:

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

These side effects may get better after you take donepezil hydrochloride for a while. This is not a complete list of side effects with donepezil hydrochloride. For more information, ask your 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 be stored?

Store donepezil hydrochloride at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

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

General information about donepezil hydrochloride

Medicines are sometimes prescribed for conditions that are not mentioned in this Patient Information Leaflet. Do not use donepezil hydrochloride for a condition for which it was not prescribed. Do not give donepezil hydrochloride to other people, even if they have the same symptoms or condition. It may harm them.

This leaflet summarizes the most important information about donepezil hydrochloride. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about donepezil hydrochloride that is written for health professionals. For more information call Alembic Pharmaceuticals Limited at 1-866-210-9797.

What are the ingredients in donepezil hydrochloride tablets, USP?

Active ingredient: donepezil hydrochloride USP

Inactive ingredients:

- **Donepezil hydrochloride film-coated tablets, USP 5 mg and 10 mg:** lactose monohydrate, corn starch, microcrystalline cellulose, hydroxypropyl cellulose, and magnesium stearate. The film coating contains talc, polyethylene glycol, hypromellose and titanium dioxide. Additionally, the 10 mg tablet contains iron oxide yellow as a coloring agent.

Medication Guide available at <http://www.alembicusa.com/medicationguide.aspx> or call 1-866-210-9797.

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