

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

- Tablets: 5 mg and 10 mg

Read the Patient Information that comes with donepezil hydrochloride before the patient starts taking it 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 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?

The patient should not take donepezil hydrochloride if allergic to any of the ingredients in donepezil hydrochloride 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.

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

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 can harm an unborn baby.
- Present breast-feeding. It is not known if donepezil hydrochloride passes into breast milk. Donepezil hydrochloride is 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 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 together may make the patient 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 the patient takes donepezil hydrochloride 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?

- Give donepezil hydrochloride exactly as prescribed by the doctor. Do not stop donepezil hydrochloride or change the dose yourself. Talk with the doctor first.
- Give donepezil hydrochloride one time each day. Donepezil hydrochloride can be taken with or without food.
- If you miss giving the patient a dose of donepezil hydrochloride, just wait. Give only the next dose at the usual time. Do not give 2 doses at the same time.
- If donepezil hydrochloride is missed for 7 days or more, talk with the doctor before starting again.
- If the patient takes too much donepezil hydrochloride at one time, call the 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 the doctor right away if the patient faints while taking donepezil hydrochloride.
- **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 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 for a while. This is not a complete list of side effects with donepezil hydrochloride. 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 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 people other than the patient, even if they have the same symptoms as the patient, as it may harm them.

This leaflet summarizes the most important information about donepezil hydrochloride. If you would like more information talk with the patient's 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.

Manufactured by:

Alembic Pharmaceuticals Limited

(Formulation Division),
Panelav 389350, Gujarat, India

Manufactured for:

Alembic Pharmaceuticals, Inc.

750 Route 202, Bridgewater, NJ 08807
USA

Revised : 05/2017

20020596