

ARICEPT PATIENT PACKAGE INSERT

ARICEPT® (Air-eh-sept)
(donepezil hydrochloride) tablets

- Tablets: 5 mg, 10 mg, and 23 mg

ARICEPT® ODT (Air-eh-sept oh-dee-tee)
(donepezil hydrochloride) orally disintegrating tablets

- ODT Tablets: 5 mg and 10 mg

Read the Patient Information that comes with ARICEPT 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 ARICEPT?

ARICEPT comes as ARICEPT film-coated tablets in dosage strengths of 5 mg, 10 mg, and 23 mg, and as ARICEPT Orally Disintegrating Tablets (ODT; 5 mg and 10 mg). Except where indicated, all the information about ARICEPT in this leaflet also applies to ARICEPT ODT.

ARICEPT is a prescription medicine to treat mild, moderate and severe Alzheimer's disease. ARICEPT can help with mental function and with doing daily tasks. ARICEPT 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

ARICEPT does not cure Alzheimer's disease. All patients with Alzheimer's disease get worse over time, even if they take ARICEPT.

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

Who should not take ARICEPT?

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

What should I tell the doctor before the patient takes ARICEPT?

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 ARICEPT can harm an unborn baby.
- Present breast-feeding. It is not known if ARICEPT passes into breast milk. ARICEPT 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. ARICEPT 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 ARICEPT together may make the patient more likely to get stomach ulcers.

ARICEPT taken with certain medicines used for anesthesia may cause side effects. Tell the responsible doctor or dentist that the patient takes ARICEPT 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 ARICEPT?

- Give ARICEPT exactly as prescribed by the doctor. Do not stop ARICEPT or change the dose yourself. Talk with the doctor first.
- Give ARICEPT one time each day. ARICEPT can be taken with or without food.
- ARICEPT 23 mg tablets should be swallowed whole without the tablets being split, crushed or chewed.
- ARICEPT ODT melts on the tongue. The patient should drink some water after the tablet melts.
- If you miss giving the patient a dose of ARICEPT, just wait. Give only the next dose at the usual time. Do not give 2 doses at the same time.
- If ARICEPT is missed for 7 days or more, talk with the doctor before starting again.
- If the patient takes too much ARICEPT 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 ARICEPT?

ARICEPT 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 ARICEPT.
- **more stomach acid.** This raises the chance of ulcers and bleeding, especially when taking ARICEPT 23 mg. 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 ARICEPT 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 ARICEPT for a while. This is not a complete list of side effects with ARICEPT. 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 ARICEPT be stored ?

Store ARICEPT at room temperature between 59° to 86°F (15° to 30°C).

Keep ARICEPT and all medicines out of the reach of children.

General information about ARICEPT

Medicines are sometimes prescribed for conditions that are not mentioned in this Patient Information Leaflet. Do not use ARICEPT for a condition for which it was not prescribed. Do not give ARICEPT 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 ARICEPT. If you would like more information talk with the patient's doctor. You can ask your pharmacist or doctor for information about ARICEPT that is written for health professionals. For more information, go to www.ARICEPT.com, or call 1-800-760-6029.

What are the ingredients in ARICEPT?

Active ingredient: donepezil hydrochloride

Inactive ingredients:

- **ARICEPT 5 mg and 10 mg film-coated tablets:** lactose monohydrate, cornstarch, microcrystalline cellulose, hydroxypropyl cellulose, and magnesium stearate. The film coating contains talc, polyethylene glycol, hypromellose, and titanium dioxide. Additionally, the 10 mg tablet contains yellow iron oxide (synthetic) as a coloring agent.
- **ARICEPT 23 mg film-coated tablets:** ethylcellulose, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate and methacrylic acid copolymer, Type C. The reddish color film coating includes ferric oxide, hypromellose 2910, polyethylene glycol 8000, talc and titanium dioxide.
- **ARICEPT ODT 5 mg and 10 mg tablets:** carrageenan, mannitol, colloidal silicon dioxide, and polyvinyl alcohol. The 10 mg tablet contains yellow iron oxide (synthetic) as a coloring agent.

ARICEPT® is a registered trademark of
Eisai Co., Ltd.

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Marketed by Pfizer Inc, New York, NY 10017

Rx Only

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