

Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 05/2017

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: Aricept D Tablets 10mg

Active ingredient: Donepezil hydrochloride

Dosage form: pale red tablet, diameter: 8.0 mm, thickness: 3.4 mm

Print on wrapping: (face) アリセプト D 錠 10mg
(back) AriceptD, 10, アリセプト D



Effects of this medicine

This medicine inhibits an enzyme which hydrolyzes the neurotransmitter acetylcholine in the brain and slows progression of the symptoms of dementia such as memory loss, repeated conversations/actions or impaired judgment.

It is usually used to slow progression of symptoms of dementia associated with Alzheimer's disease or Lewy body dementia.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
If you have heart diseases such as sick sinus syndrome, sinoatrial block, atrioventricular block, Parkinson's disease/syndrome or history of gastric/duodenal ulcer.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- For slowing progression of symptoms of dementia associated with Alzheimer's disease: In general, for adults, give 3 mg as the active ingredient at a time once a day for the first one to two weeks. Subsequently, the dose will be increased to 5 mg at a time once a day. Additionally, if the disease has progressed, after giving 5 mg at a time once a day for more than 4 weeks, the daily dose will be increased to 10 mg at a time once a day. The dosage should be adjusted according to the symptoms.
For slowing progression of symptoms of dementia associated with Lewy body dementia: In general, for adults, give 3 mg as the active ingredient at a time once a day for the first one to two weeks. Subsequently, the dose will be increased to 5 mg at a time once a day. Additionally, after giving 5 mg at a time once a day for more than 4 weeks, the daily dose will be increased to 10 mg at a time once a day. The dosage may be decreased to 5 mg at a time once a day according to the symptoms.
This preparation contains 10 mg of the active ingredient in a tablet. In any case, strictly follow the instructions.
- If the dosage is increased to 10 mg at a time once a day, pay attention to gastrointestinal adverse reactions.
When giving this medicine, place the tablet in the patient's mouth and allow it to dissolve, and then let it swallow with or without a half-glass of water. This medicine should not be taken without water when the patient is lying down.
- If you miss giving a dose, give a dose as soon as you notice it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should never give two doses at one time.
- If you accidentally give more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop giving this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- In patients with Alzheimer's disease or Lewy body dementia, the ability to operate machinery such as driving a car may diminish. Since disturbance of consciousness, dizziness or drowsiness may occur, do not engage the patient in the operation of dangerous machinery such as driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, itch, loss of appetite, nausea/vomiting, diarrhea, abdominal pain, agitation, restlessness, insomnia and wandering. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- loss of consciousness, chest pain, shortness of breath [QT prolongation, ventricular tachycardia, ventricular fibrillation, sick sinus syndrome, sinus pause, severe bradycardia, syncope, heart block, myocardial infarction,

heart failure]

- heartburn, abdominal pain, black stool, bloody stool, fever [peptic ulcer, duodenal ulcer perforation, gastrointestinal hemorrhage]
- nausea/vomiting, loss of appetite, yellowing of the skin or whites of the eyes [hepatitis, hepatic dysfunction, jaundice]
- convulsion, severe headache, nausea/vomiting [cerebral seizure, cerebral hemorrhage, cerebrovascular disorder]
- slow movement, involuntary movement of the mouth/tongue/limbs, abnormal muscular contraction, shaking of the limbs [extrapyramidal disorder]
- high fever, muscle stiffness, semi-consciousness [malignant syndrome]
- muscle pain, lassitude, reddish brown urine [rhabdomyolysis]
- shortness of breath, breathing difficulty [respiratory distress]
- upper abdominal/lower back pain, nausea/vomiting [acute pancreatitis]
- general edema, decreased urine output [acute kidney injury]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Ask the pharmacist and the medical institution how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.