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

Internal
Revised: 04/2019

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:DONEPEZIL HYDROCHLORIDE OD TABLETS 3mg 「OHARA」

Active ingredient: Donepezil hydrochloride

Dosage form:yellow tablet, diameter: 8.0 mm, thickness: 3.3 mm

Print on wrapping:ドネペジル塩酸塩 OD3 mg「オーハラ」, 口腔内崩壊錠, Donepezil Hydrochloride OD 3 mg「OHARA」, 3 mg

Effects of this medicine

This medicine suppresses actions of enzymes which degrade acetylcholine, neurotransmitter in the brain, and it consequently delays progression of the symptoms of dementia such as memory loss, repetition of behavior and impaired judgment.

It is usually used to inhibit progression of symptoms in Dementia Alzheimer's type or Dementia with Lewy bodies.

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

- If you have previously experienced any allergic symptoms such as itching and rash.
  If you have : heart diseases such as sick sinus syndrome, sinoatrial block and atrioventricular block, Parkinson's disease, Parkinson's syndrome, or a history of gastric ulcer or 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))
- Progression suppression of dementia symptoms in Dementia Alzheimer's type:
  in general, for adults, start with giving 3 mg as the active ingredient at a time, once a day. Then the dosage will be increased to 5 mg once a day after one or two weeks of the starting administration.
  Additionally, if the disease has progressed to the late stage, after giving 5 mg for more than 4 weeks, the daily dose is increase to 10 mg once a day, however, the dosage may be decreased according to the symptoms.
- Progression suppression of dementia symptoms in Dementia with Lewy bodies:
  in general, for adults, start with giving 3 mg as the active ingredient at a time, once a day. Then the dosage will be increased to 5 mg once a day after one or two weeks of the starting administration.
  After giving 5 mg for more than 4 weeks the daily dose is increase to 10mg once a day, however, the dosage may be decreased to 5 mg at a time once a day according to the symptoms.
  This preparation contents 3 mg of the active ingredient in a tablet. Strictly follow the instructions in any case.
- In case of increase to 10 mg once a day, keep watch on the patient's gastrointestinal symptoms due to adverse reaction of the medicine.
- When giving this medicine, put it in the patient's mouth and disintegrate it with saliva and swallow it or giving it with a half glass of water. This medicine should not be given without water when the patient is lying down.
- If you missed giving a dose, give the missed dose as soon as possible. However, if more than half a day has passed from the scheduled time, skip the missed dose and follow the 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 Dementia Alzheimer's type or Dementia with Lewy bodies, the ability to operate machinery such as driving a car diminish gradually and this medicine may cause disturbed conscious, dizziness and sleepiness. Do not engage the patient in operating 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 poriomania. 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.

- ・syncope, chest pain, shortness of breath [QT prolongation, ventricular tachycardia, ventricular fibrillation, sick sinus syndrome, sinus arrest, severe bradycardia, syncope, heart block, myocardial infarction, cardiac failure]
- ・heartburn or abdominal pain, black stool or bloody stool, fever [peptic ulcer, duodenal ulcer with perforation, gastrointestinal bleeding]
- ・nausea or vomiting, loss of appetite, yellow discoloration of the skin/white of the eyes [hepatitis, liver dysfunction, jaundice]
- ・convulsion, severe headache, nausea or vomiting [cerebral attack, cerebral bleeding, cerebrovascular disorder]
- ・slow movements, involuntary movements of mouth, tongue and limbs, abnormal muscle contraction, shivering of 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 pain or lower back pain, nausea or vomiting [acute pancreatitis]
- ・general edema, decreased urine output [acute renal disorder]

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 the reach of children. Store away from light, heat and moisture.
- ・Discard the remainder. Do not store them. Ask the pharmacist or medical institution on how to discard the remainder.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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