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 TABLETS 5mg「OHARA」

Active ingredient: Donepezil hydrochloride

Dosage form:white tablet, diameter: 7.1 mm, thickness: 3.7 mm

Print on wrapping:ドネペジル塩酸塩 5mg「オーハラ」, ドネペジル 5mg, オーハラ, Donepezil Hydrochloride5mg「OHARA」, 5mg

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 10 mg once a day, however, the dosage may be decreased to 5mg at a time once a day according to the symptoms.

This preparation contents 5 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.

・If you miss giving a dose, give a dose as soon as possible. However, if it already has passed half a day of the scheduled time, skip the missed dose and continue 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 abdomen pain, black stool or melaena, fever [peptic ulcer, duodenal ulcer perforation, digestive tract hemorrhage]
- nausea or vomiting, loss of appetite, yellowing in skin and white of eyes [hepatitis, hepatic dysfunction, jaundice]
- convulsion, severe headache, nausea, vomiting [cerebral seizure, cerebral hemorrhage, cerebrovascular disorder]
- slowness of movement; involuntary movement of the mouth, tongue and limbs; abnormal muscular contraction; tremor of limbs [extrapyramidal disorder]
- high fever, muscle stiffness, twilight state [malignant syndrome]
- muscle pain, muscle weakness, reddish brown urine [rhabdomyolysis]
- shortness of breath, breathing difficulty [dyspnea]
- upper abdominal pain, lower back pain, nausea, vomiting [acute pancreatitis]
- generalized swelling, 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 direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Ask the pharmacy or medical institution how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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