

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

Internal

Published: 06/2020

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:MEMANTINE HYDROCHLORIDE OD TABLETS 5mg

「OHARA」

Active ingredient:Memantine hydrochloride

Dosage form:pale reddish white tablet, diameter: 8.1 mm, thickness: 3.9 mm

Print on wrapping:メマンチン塩酸塩 OD5mg「オーハラ」、メマンチン、OD、5mg、口腔内崩壊錠、Memantine hydrochloride OD 5mg「OHARA」



Effects of this medicine

This medicine suppresses an excessive influx of calcium ions into cells by inhibiting excessive activation of NMDA receptor channels, intracerebral glutamate receptor subtypes. It consequently suppresses nerve cell damage and memory/learning disorder.

It is usually used to suppress progression of dementia symptoms in moderate to severe Alzheimer-type 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 a history of epilepsy or convulsion.
If you have renal dysfunction, renal tubular acidosis, urinary tract infection or hepatic dysfunction.
- 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))
- In general, for adults, start with giving 1 tablet (5 mg of the active ingredient) at a time, once a day. Then the dose will be increased by 1 tablet (5 mg) per week, and give 20 mg at a time, once a day from the 4th week. Strictly follow the instructions.
- Since this medicine will disintegrate if it is put on a tongue and makes saliva permeate, it can be given without water. It can also be given with water.
This medicine should not be given without water while in lying position.
- If you miss a dose, give the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue the patient's regular dosing schedule. You should never give two doses at one time.
- If you accidentally give more than your prescribed dose, consult with the doctor or pharmacist.
- Do not stop giving this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- Be aware that this medicine may cause dizziness at the initial stage of administration.
- In patients with moderate to severe Alzheimer-type dementia, the ability to operate dangerous machinery such as driving a car may decline. This medicine may also cause drowsiness or dizziness. Pay attention not to let the patient operate dangerous machinery such as driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dizziness, constipation, body weight loss, headache, loss of appetite, increased blood pressure, fall and edema. 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.

- muscle spasmodically contracting [convulsion]
- fainting [syncope, loss of consciousness]
- overexcited (emotionally hyper and loud), aggressive or attacking behavior towards self or others, subjective delusion without evidence [psychological symptoms (agitation, aggression, delusion, hallucination, confusion,

delirium)]

- general malaise, loss of appetite, yellowing of skin or the white of eyes [liver dysfunction, jaundice]
- muscle pain, muscle weakness, reddish brown urine [rhabdomyolysis]

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. Consult with your pharmacy or medical institution about how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

SIE①