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

Internal Revised: 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: MEMARY TABLETS 20mg**

Active ingredient: Memantine hydrochloride

**Dosage form:** white to yellowish white oval tablet, major axis: 12.1 mm, minor axis: 6.1

mm, thickness: approx.4.4 mm

Imprint or print on wrapping:メマリー錠 20mg, Memary 20mg

#### Effects of this medicine

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

It is usually used for suppressing progression of symptoms of dementia in moderate to severe Alzheimer-type dementia.

## The following patients may need to be careful when 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 or foods.

  If you have: a history of epilepsy or convulsion, 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 5 mg of the active ingredient at a time, once daily. Then the dose will be increased by 5 mg per week, and give 20 mg at a time, once daily in and after week 4. This preparation contains 20 mg of the active ingredient in a tablet. Strictly follow the instructions.
- •If you miss a dose, give a 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

- ·Attention is demanded because the medicine may cause dizziness in the initial period of taking.
- •In a patient with moderate to severe Alzheimer-type dementia, the ability of operating dangerous machinery such as driving a car may decline. The medicine may cause dizziness or drowsiness. Do not 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, increase in blood pressure, fall, edema, gait abnormality and hallucination. 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 or attitude towards others or self, subjective delusion without evidence [psychological symptom (agitation, aggression, delusion, hallucination, confusion, delirium)]
- ·general dullness, loss of appetite, yellowing of the skin or white eyes [liver dysfunction, jaundice]
- ·muscle pain, muscle weakness, reddish brown urine [rhabdomyolysis]
- •shortness of breath, dizziness, loss of consciousness [bradyarrhythmia such as complete atrioventricular block, severe bradycardia]

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 pharmacist or medical institution on how to discard the remainder.

For healthcare professional use only

For further information, talk to your doctor or pharmacist.