

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

Internal

Revised: 11/2016

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: Carbamazepine Tablets 100mg "AMEL"

Active ingredient: Carbamazepine

Dosage form: white to faintly yellowish white tablet, diameter: approx. 8.0mm, thick: approx. 2.3mm

Print on wrapping: (face) カルバマゼピン 100mg「アメル」 カルバマゼピン 100 KW161,
(back) Carbamazepine100mg《AMEL》 カルバマゼピン「アメル」
100mg CBZ100



Effects of this medicine

This medicine suppresses epileptic seizures by sedating excessive excitation of nerves in the brain. It also suppresses excessive high tension by its sedative effect. It suppresses abnormal excitation of trigeminal nerve in face to relieve the attacks of trigeminal neuralgia.

It is usually used to treat epilepsy, manic state in such as manic-depressive psychosis, or trigeminal neuralgia.

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 blood disorder, atrioventricular block, bradycardia, or porphyria.
- 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))
- Psychomotor seizure, mental disorder with epilepsy, epileptic convulsive attack: In general, for adults, initially take 2 to 4 tablets (200 to 400 mg of the active ingredients) a day, to be taken in 1 to 2 divided doses, and gradually increase to 6 tablets (600 mg) a day until the effect of the medicine is obtained. The daily dosage may be increased up to 12 tablets (1,200 mg) according to the symptoms. For children, take 1 to 6 tablets (100 to 600 mg of the active ingredients) a day in some divided doses according to the age or symptoms.
- Mania, manic state of bipolar disorder, excited state of schizophrenia: In general, for adults, initially take 2 to 4 tablets (200 to 400 mg of the active ingredients) a day, to be taken in 1 to 2 divided doses, and gradually increase to 6 tablets (600 mg) a day until the effect of the medicine is obtained. The daily dosage may be increased up to 12 tablets (1,200 mg) according to the symptoms.
- Trigeminal neuralgia: In general, for adults, initially take 2 to 4 tablets (200 to 400 mg of the active ingredients), and gradually increase to 6 tablets (600 mg) a day in some divided dose. The daily dosage may be increased up to 8 tablets (800 mg) according to the symptoms. For children, the dose is decreased according to the age or symptoms. In any case, strictly follow the instructions.
- If you miss a dose, take a dose as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so. In treatment for epilepsy, sudden withdrawal may cause successive seizures.

Precautions while taking this medicine

- Pay close attention in starting and increasing the medicine, as it tends to cause drowsiness, nausea, dizziness, etc.
- The medicine may cause drowsiness and decreased attention. Do not drive a car or operate dangerous machinery.
- Avoid drinking alcohol as possible, since it may intensify drowsiness.
- Avoid drinking grapefruit juice as it may strengthen the effect of the medicine.
- Avoid taking health foods containing St. John's wort as it may weaken medicinal effects.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include drowsiness, dizziness, light-headedness, malaise/fatigability, ataxia (motor incoordination), lassitude, rash, headache/dull headache, dizziness on standing up, dry mouth (thirst), angioedema (swelling in face/tongue/throat), itch, photosensitivity, hives, flush, vasculitis, breathing difficulty, lymph gland swelling, porphyria, anemia and pancreatitis. 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.

- pain in throat, bleeding tendency, symptom of anemia [blood disorder such as aplastic anemia, agranulocytosis]
- fever, rash/blister in skin, bloodshot eyes, erosion in lips/mouth [toxic epidermal necrolysis, mucocutaneous ocular syndrome, acute generalized exanthematous pustulosis, erythroderma(exfoliative dermatitis)]
- fever, rash, swelling in lymph node [hypersensitivity syndrome]
- loss of appetite, general malaise, yellowness in skin or conjunctiva [hepatic dysfunction, jaundice]
- dizziness, faint, bradycardia [congestive heart failure, atrioventricular block, sinus node dysfunction, 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.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.