

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

Internal

Revised: 03/2022

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: AMOXAN CAPSULES 25mg

Active ingredient: Amoxapine

Dosage form: pale reddish brown/white capsule, major axis: 14.4 mm, minor axis: 5.3 mm, weight: 220 mg

Print on wrapping: (Face) Amoxan 25mg, 25mg, アモキササン, (Back) アモキササン 25mg, アモキサピン, LL146



Effects of this medicine

This medicine inhibits reuptake of an intracerebral transmitter (catecholamine) to the brain neuron to increase catecholamine level in the synapse and to improve feeling of gloom or depression. It is usually used to treat depression/depressive states.

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

- If you have previously experienced any allergic reactions (itching, rash, etc.) to any medicines. If you have angle closure glaucoma, urination difficulty or increased intraocular pressure, etc., open angle glaucoma, cardiac disorder (except patients in early recovery period of myocardial infarction) such as cardiac failure/myocardial infarction/angina pectoris/arrhythmia (paroxysmal tachycardia/conduction disorder, etc.) or hyperthyroidism, convulsive disease such as epilepsy or history of it, manic depression, suicidal ideation or history of it, history of suicide attempt, predisposing factors of organic brain disorder or schizophrenia or highly impulsive comorbid disorder.
- If you are in early recovery period of myocardial infarction.
- If you discontinued taking monoamine oxidase inhibitor within the past 2 weeks.
- 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, take 1 to 3 capsules (25 to 75 mg of the active ingredient) in 1 to several divided doses per day. If it is considered the effect is not sufficient, the dosage may be increased up to 6 capsules (150 mg) per day. If the symptoms are particularly severe, it may be increased up to 12 capsules (300 mg) per day. Strictly follow the instructions.
- Sudden decrease in the dosage and discontinuation of this medicine may cause withdrawal symptoms (dysphoria, chills, confusion, headache, sleep disorder, malaise, nausea, sweating, etc.).
- If you miss a dose, take the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and follow 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.

Precautions while taking this medicine

- This medicine may cause drowsiness or decreased attention/concentration/reflex action ability. Avoid operating dangerous machinery, such as driving a car, or working at heights.
- Pay attention that alcohol may intensify medicinal or medical effects.
- This medicine may cause worsening symptoms of the disease, suicidal thoughts/suicide attempt and harming others, though causal relationships between them are unknown. If any of these signs occur, consult with your doctor or pharmacist without stopping your medication.

Possible adverse reactions to this medicine

The reported adverse reactions include dry mouth, constipation, dizziness, drowsiness, urination difficulty, hypouresis, vision adjustment disorder, nasal congestion, increased intraocular pressure, rash, edema of face/tongue, erythema and itching. 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.

- akinetic mutism (motionless), difficulty in swallowing, tachycardia (fast pulse) [neuroleptic malignant syndrome]

- muscle spasmodically contracting, impaired mind, seeing thing/hearing sound that does not really exist [convulsion, mental confusion, hallucination, delirium]
- fever, sore throat, flu like symptoms [agranulocytosis]
- loss of appetite, nausea, severe constipation [paralytic ileus]
- involuntary movement around the mouth (moving tongue, sticking tongue in and out, continuous chewing movement) [tardive dyskinesia]

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 reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Seek advice of your pharmacy or medical institution about proper disposal of the unused medicines.
- [To family members] This medicine may cause change in patient's behavior such as suicide, tendency to excite, acting aggressively and change in mental or physical condition due to slight irritation, and worsening of the underlying disease such as depression. Receive an adequate explanation from the doctor for full understanding of these risks and observe change in the patient's condition. If family members notice any of these conditions, contact the doctor.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.