

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

Internal

Revised: 10/2016

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: Diazepam Tablets 2mg "AMEL"

**Active ingredient:** Diazepam

**Dosage form:** white tablet, diameter: approx. 7.0 mm, thick: approx. 1.95 mm

**Print on wrapping:** (face) ジアゼパム 2mg「アメル」 ジアゼパム「アメル」 KW231 〈2〉,  
(back) Diazepam 2mg《AMEL》 ジアゼパム「アメル」 KW231 2



## Effects of this medicine

This medicine is a drug of the benzodiazepine group that relieves anxiety, tension, etc. and improves symptoms of muscle spasms.

It is usually used for treatment of anxiety, tension, depression, etc., for control of seizures, for sedation before anesthesia, etc.

## 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 glaucoma, myasthenia gravis, heart diseases, liver disorder, renal disorder, brain disorder or respiratory diseases.
- If you are debilitated.
- 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, take 1 to 2.5 tablets (2 to 5 mg of the active ingredient) at a time, 2 to 4 times a day. If you are an outpatient, the dosage should not be more than 7.5 tablets (15 mg) a day. For children 3 years of age or younger, take 1 to 5 mg of the active ingredient a day, and for children 4 to 12 years of age, take 2 to 10 mg of the active ingredient a day, to be taken in 1 to 3 divided doses.  
For treatment of muscle spasm: In general, for adults, take 1 to 5 tablets (2 to 10 mg of the active ingredient) at a time, 3 or 4 times a day. The dosage should be adjusted according to age or symptoms.  
For preanesthetic medication: In general, for adults, take 2.5 to 5 tablets (5 to 10 mg of the active ingredient) at a time, before bedtime or surgery. The dosage should be adjusted according to age or symptoms.  
Each tablet contains 2 mg of the active ingredient. Strictly follow the instructions in any of these cases.
- If you miss a dose, take the missed dose as soon as possible. If there is less than 4 hours to the next dose, skip the missed dose and take the next dose at your regular time. 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, and lack of attention, concentration and reflex action ability, etc. Do not operate dangerous machinery such as driving a car while taking the medicine.
- Refrain from alcohol drinking while taking the medicine because the effect of the medicine may be potentiated by alcohol.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include drowsiness, light-headedness, dizziness, gait ataxia, headache, incontinence, impaired speech, trembling, tachycardia, decreased blood pressure, nausea, vomiting, loss of appetite, constipation, dry mouth, rash, malaise, lassitude, edema and jaundice. 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.**

- convulsion/trembling, insomnia/anxiety, hallucination/delusion [drug dependence/withdrawal symptoms due to prolonged use in large doses]
- excitement, confusion [irritable excitation, confusion]
- breathlessness [respiratory depression]

**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.