

# 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: Quazepam tablets 15mg "AMEL"

**Active ingredient:** Quazepam

**Dosage form:** pale yellow-red tablet, diameter: approx. 7.0mm, thick: approx. 2.4mm

**Print on wrapping:** (face)クアゼパム 15mg「アメル」, クアゼパム, 15mg「アメル」, 15, KW168  
(back)QUAZEPAM15mg《AMEL》, クアゼパム 15mg「アメル」



## Effects of this medicine

This medicine exerts hypnotic and sedative effects by acting on benzodiazepine receptors in the brain. It also enhances the effects of sleep by acting on the nervous system involved in sleep.

It is usually used for the treatment of insomnia, and as an anesthetic premedication.

## 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, sleep apnea syndrome, decreased respiratory function caused by cor pulmonale, pulmonary emphysema, bronchial asthma, acute phase of cerebrovascular disorder, etc.
- 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>>
- **Insomnia:** In general, for adults, take 20 mg of the active ingredient at a time, immediately before bedtime. It should be adjusted according to the disease, age and symptoms, however, the dosage should not be more than 2 tablets (30 mg of the active ingredient) a day.  
**Preanesthesia:** In general, for adults, take 1 to 2 tablets (15 to 30 mg of the active ingredient) at a time, before bedtime on the evening before surgery. It should be adjusted according to the disease, age and symptoms, however, the dosage should not be more than 2 tablets (30 mg) a day.  
This preparation contains 15 mg of the active ingredient in a tablet. In any case, strictly follow the instructions.
- Take this medicine just before going to bed on an empty stomach, do not take any food after taking the medicine.  
Food in the stomach may intensify the effect of this medicine.
- Do not take this medicine if you need to get up to do some work after sleeping for a few hours.
- If you miss a dose, take a dose as soon as possible. However, take the medicine enough time apart after meals because the effect of the medicine may increase after meals.
- 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

- The medicine may cause drowsiness; or decline of ability to pay attention, to concentrate or reflex movement even in the next morning. Avoid driving a car or operating dangerous machinery after taking the medicine.
- Drinking alcohol may enhance the effect of the medicine. Avoid drinking alcohol while you are receiving the medicine.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include drowsiness, dizziness, nausea and malaise. 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.**

- unable to control desire to the medicine, (when you stop taking the medicine) convulsion, insomnia, anxiety [drug dependence]
- confused/disturbed consciousness, impaired mind, unable to recognize time or place [irritable excitation, confusion]
- shallow and rapid breathing, shortness of breath, consciousness disorder [respiratory depression, carbon dioxide narcosis]
- audio-visual experience of something that does not exist, impaired mind, tendency to excite [mental disorder (convulsion, hallucination, etc.), consciousness disorder, thought disorder, excitement, delirium]
- erectile dysfunction, inability to exercise or speak well, trembling of limbs [erectile dysfunction, ataxia, decline in

the psychomotor function, coordination disturbance, impaired speech, tremor]

- no memory before sleep or during awakening at nighttime, semi-consciousness [transient anterograde amnesia, semi-consciousness]

**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 light, heat and moisture.
- Discard the remainder. Do not store them.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.