

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

Internal

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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:** Quetiapine Fine Granules 50% "AMEL"

**Active ingredient:** Quetiapine fumarate

**Dosage form:** white fine granules

**Print on wrapping:**



## Effects of this medicine

This medicine acts on dopamine, serotonin and various other receptors in the brain, thus improving the symptoms of strong anxiety and/or a tense feeling and decreased motivation.

It is usually used for the treatment of schizophrenia.

## 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 a current or past history of diabetes mellitus.
- 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 0.05 g (25 mg of quetiapine) at a time, twice or three times per day, and the dose may be gradually increased depending on the patient's condition up to 0.3 to 1.2 g (150 to 600 mg of quetiapine) per day taken in 2 or 3 divided doses. The dosage may be adjusted according to the patient's age and symptoms; however, the total daily dose should not exceed 1.5 g (750 mg of quetiapine). Strictly follow the instructions.
- 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 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.

## Precautions while taking this medicine

- Sleepiness and a decrease in attention, concentration, and reflex movement, etc. may occur. Do not drive a car, work at heights or operate dangerous machinery.
- You may experience weight gain. Pay attention to your diet or exercise therapy and try not to become obese.
- Alcohol intake may enhance the effect of the medicine. Refrain from alcohol drinking while taking the medicine.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include sleep loss, drowsiness, malaise, anxiety and irritability. 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.**

- thirst, excessive drinking/polyuria, pollakiuria [hyperglycemia, diabetic ketoacidosis, diabetic coma]
- feelings of weakness, cold sweat, tremor of the hands and legs [hypoglycemia]
- muscle stiffness, difficulty with swallowing, sweating [malignant syndrome]
- myalgia, feelings of weakness, reddish brown urine [rhabdomyolysis]
- spasm [convulsions]

**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. Consult with your dispensing pharmacy or medical institution how to discard.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.