

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

Internal

Revised: 10/2023

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:Seroquel Fine Granules 50%

Active ingredient:Quetiapine fumarate

Dosage form:white fine granules

Imprint or 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.

The following patients may need to be careful when 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 or foods.
If you are in a coma.
- If you have or have a history of diabetes mellitus.
- If you have or are suspected to have heart/vascular disease, cerebrovascular disorder or hypotension.
- If you have or have a history of convulsive disease such as epilepsy.
- If you have or have a history of arrhythmia.
- If you have congenital long QT syndrome.
- If you have a history of suicide attempt or have suicidal ideation.
- If you have any risk factor for diabetes mellitus such as a family history of it, hyperglycemia or obesity.
- If you have any risk factor of being in a state of immobilization, long-term bedridden, obesity or dehydration.
- If you have liver dysfunction.
- 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 3 times a day, and the dose may be gradually increased depending on the condition up to 0.3 to 1.2 g (150 to 600 mg) a day taken in 2 or 3 divided doses. The dosage may be adjusted according to the age or symptoms; however, the total daily dose should not exceed 1.5 g (750 mg). 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 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 sleepiness, decrease in attention/concentration/reflex movement, etc. Do not operate dangerous machinery, such as driving a car.
- You may experience weight gain. Pay attention to your diet or exercise therapy and try not to become obese.
- Since this medicine may cause a critical condition such as diabetic ketoacidosis or diabetic coma which could lead to death, or it may cause hypoglycemia, blood glucose levels may be measured while using this medicine. The patients and their family should receive enough explanation about such adverse reactions from the doctor until they fully understand it. If any symptom of adverse reactions is observed in the patient, stop using this medicine and visit the doctor immediately.
- Since agranulocytosis or leukopenia may occur, blood tests may be performed while using this medicine.
- Alcohol intake may enhance the effect of this medicine. Refrain from alcohol drinking while taking the medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include insomnia, irritability, somnolence, anxiety, headache, dizziness, akathisia (cannot remain still), trembling limbs, articulatory disorder (awkward way of speaking), tachycardia, constipation, loss of appetite, malaise and asthenia. 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, trembling limbs [hypoglycemia]
- muscle stiffness, difficulty in swallowing, sweating [neuroleptic malignant syndrome]
- muscle pain, feelings of weakness, reddish brown urine [rhabdomyolysis]
- convulsions [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 reach of children. Store at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard, seek advice of your dispensing pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.