

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: Zyprexa Zydys Tablets 10mg

Active ingredient: Olanzapine

Dosage form: yellow tablet, diameter: 11 mm, thickness: 2.7 mm

Imprint or print on wrapping: ジプレキサ ザイデイス 10mg



Effects of this medicine

This medicine acts on receptors for neurotransmitter in brain, and regulates the function of neurotransmitters. It is usually used to improve symptoms such as hallucination/delusion and anxiety or irritability, and to stabilize mood.

It also improves manic symptoms such as uncontrollable excitation and behavior and depressive symptoms such as depressed mood in bipolar disorder.

Besides these, this medicine is used in case of gastrointestinal symptoms (nausea and vomiting) associated with chemotherapy medicine (such as cisplatin) for cancer.

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 diabetes mellitus or a history of it.
- 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))
 - For schizophrenia: In general, for adults, start taking 5 to 10 mg of the active ingredient at a time, once a day. The dosage is maintained on 1 tablet (10 mg) once a day. It may be adjusted according to your age and symptoms. However, the maximum daily dosage is up to 2 tablets (20 mg).
 - For improvement of manic symptoms in bipolar disorder: In general, for adults, start taking 1 tablet (10 mg of the active ingredient) at a time, once a day. The maintenance dosage may be adjusted according to your age and symptoms. However, the maximum daily dosage is up to 2 tablets (20 mg).
 - For improvement of depressive symptoms in bipolar disorder: In general, for adults, start taking 5 mg of the active ingredient at a time, once a day, and then the dosage is increased to 1 tablet (10 mg of the active ingredient) once a day at bedtime in either case. The dosage may be adjusted according to your age and symptoms. However, the maximum daily dosage is up to 2 tablets (20 mg).
 - For gastrointestinal symptoms (nausea and vomiting) associated with chemotherapy medicine (such as cisplatin) for cancer: In general, for adults, take 5 mg of the active ingredient at a time, once a day in combination with other antiemetics. The dosage may be increased according to your condition. However, the maximum daily dosage is up to 1 tablet (10 mg).
- In any case, strictly follow the instructions.
- The tablet immediately dissolves in your mouth. Then, swallow it with saliva or water.
 - When a tablet was chipped and/or cracked, take all chips/cracks of tablet (as this tablet is fragile compared with other normal tablet, the tablet may be broken if you try to push it through the foil without peeling back the foil on the blister.).
 - Using dry hands, remove the tablet from the package immediately before taking it and take it quickly.
 - If you miss a dose, take the missed dose as soon as you remember. If it is almost time for the next dose, just 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

- The medicine may cause sleepiness, dizziness, dizziness on standing up, light-headed feeling, and decreased attention/concentration/reflex action ability. Do not work at heights or operate dangerous machinery such as driving a car.
- Please note that alcohol drinking may intensify the effect of the medicine.
- Please note that smoking may weaken the effect of the medicine.

- The medicine may cause weight gain. If you feel an increasing in your body weight, check with your doctor/pharmacist, then take action(s) for weight control such as improvement of dietary balance and exercising.
- Patients with depressive symptoms in bipolar disorder may show behavioral changes such as suicidal ideation or aggression due to the nature of this disease. Therefore, patients and family members should keep close contact with your doctor.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include somnolence, weight increase, insomnia, akathisia (state of restlessness), thirstiness, malaise and constipation. The adverse reactions to be stopped taking this medicine, when any abnormalities occur, include hyperglycemia, diabetic ketoacidosis, diabetic coma, hypoglycemia, neuroleptic malignant syndrome, rhabdomyolysis, paralytic ileus, pulmonary embolism, deep vein thrombosis and drug-induced hypersensitivity syndrome. 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.

- dry mouth, excessive fluid intake, excessive urination [hyperglycemia, diabetic ketoacidosis, diabetic coma]
- lassitude, malaise, cold sweat [hypoglycemia]
- acute fever, rapid pulse, muscle stiffness [neuroleptic malignant syndrome]
- muscle pain, lassitude, reddish brown urine [rhabdomyolysis]
- nausea, severe constipation, abdominal bloating [paralytic ileus]

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. If you do not know how to discard, seek advice of your 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.