

# 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: ARIPIRAZOLE OD TABLETS 6mg 「OHARA」

**Active ingredient:** Aripiprazole

**Dosage form:** white tablet, diameter: 7 mm, thickness: 2.6 mm

**Print on wrapping:** アリピプラゾール OD6 mg「オーハラ」, 6 mg, 口腔内崩壊錠,  
Aripiprazole OD6 mg「OHARA」



## Effects of this medicine

This medicine acts on receptors for dopamine, a neurotransmitter in the brain, to suppress symptoms such as hallucination and delusion and to stabilize unstable mental status. It also improves conditions such as decreased motivation and loss of interest, and symptoms such as uncontrollable excitation and behaviors.

It is usually used to treat 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, or have a past medical or family history of diabetes mellitus.
- If you have liver disorder, cardiovascular disease or hypotension.
- If you have or have a history of convulsive disease such as epilepsy.
- If you have attempted suicide or are considering suicide.
- 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 taking 1 to 2 tablets (6 to 12 mg of the active ingredient) a day, then take 1 to 4 tablets (6 to 24 mg) a day as a maintenance dose, in 1 to 2 divided doses. The dosage may be adjusted according to age or symptoms. However, the daily dose should not exceed 5 tablets (30 mg).
- This medicine contains 6 mg of the active ingredient in a tablet. In any case, Strictly follow the instructions.
- You may take this medicine without water since the tablet melts once you put it in the mouth. Swallow it with saliva or water. Never take this medicine without water when you are in lying position.
- If you miss a dose, take the missed dose as soon as possible. However, 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 drowsiness and decreased attention/concentration/reflex movement. Do not operate dangerous machinery, such as driving a car.
- Pay attention that alcohol (drinking) may intensify medicinal effects.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include insomnia, nervousness, akathisia (unable to keep still), tremor (shivering of limbs), anxiety, weight loss, muscle rigidity, loss of appetite, increased appetite, malaise, somnolence, hypokinesia (expressionless face), salivation (drooling), weight gain, nausea, vomiting, dystonia (muscle tone abnormalities) and constipation. 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 intake of water, excessive urination [diabetic ketoacidosis, diabetic coma]
- being silent without moving, muscle stiffness, acute fever [malignant syndrome]
- moving the tongue, moving the tongue in and out, constant chewing motion of the mouth [tardive dyskinesia]
- nausea/vomiting, no output of stool, severe abdominal pain [paralytic ileus]
- lassitude, muscle pain, reddish brown urine [rhabdomyolysis]

**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. Ask your pharmacy or medical institution on how to discard the remainder.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.

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