

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

Internal

Revised: 10/2012

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: Aldactone-A Tablets 25mg

**Active ingredient:** Spironolactone

**Dosage form:** white tablet,  $\phi$  7.0 mm, thickness 3.0 mm

**Print on wrapping:** アルダクトン A25mg, (スピロノラクトン), SEARLE101



## Effects of this medicine

This medicine lowers blood pressure and removes body swelling by promoting the excretion of sodium and water and inhibiting the excretion of potassium in the kidney with increased urine volume and excreted the extra body water. Usually, used for treatment of hypertension and cardiac edema (congestive heart failure), hepatic edema or renal edema. Also used for diagnosis of and relief of symptoms in primary aldosteronism.

## 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: anuria or acute renal failure, hyperkalemia, Addison disease, cardiac disease, coronary or cerebral arterial sclerosis, renal disorder, or liver disorder.  
If you are on low-salt diet.
- 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, take 2-4 tablets (50-100 mg of the active ingredient) per day in divided doses, to be adjusted according to your age and symptoms. Strictly follow the instructions.
- Avoid taking this medicine after supper unless your doctor instructs you to do so since it may cause frequent urination and disturb your sleep during the night.
- 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 the medicine unless your doctor instructs you to do so.

## Precautions while taking this medicine

- Dizziness or light-headed feeling may occur by declining blood pressure after taking the medicine. Be aware of driving a car, working at heights or operating dangerous machinery.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include breast swelling of male, breast pain, swollen breast, impotence (male), excess hair, menstrual irregularity, loss of menstruation, genital bleeding after menopause, deepening of the voice, rash, hives, itching, loss of appetite, nausea, dry mouth, diarrhea, constipation, dullness, palpitation, fever, and freckle. 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.**

- arrhythmia/chest pain, dullness (general), lassitude [electrolyte abnormality (e.g. hyperkalemia, hyponatremia, metabolic acidosis)]
- decreased urination output, swelling of hands/feet and face, headache [acute renal failure]
- rash, mucosal erosion/blister, high fever [toxic epidermal necrolysis, Stevens-Johnson syndrome]

**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 humidity.
- Discard the remainder. Do not store them.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.