

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

Internal

Revised: 10/2022

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, diameter: 7.0 mm, thickness: 3.0 mm

**Imprint or print on wrapping:**Aldactone-A 25mg, アルダクトン A 25mg, スピロノラクトン, SEARLE 101



## Effects of this medicine

This medicine promotes the excretion of sodium and water and inhibits the excretion of potassium in the kidney by increasing urinary output. It thereby increases urinary output and excretes extra body water leading to lowering blood pressure and removing general edema.

It is usually used to treat hypertension (essential, renal, etc.), cardiac edema (congestive heart failure), renal edema, hepatic edema, idiopathic edema, edema and ascites associated with malignant tumor or trophedema, or to diagnose primary aldosteronism and improve the symptoms.

## 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 have: anuria or acute renal failure, hyperkalemia, Addison disease, coronary or cerebral arterial sclerosis, renal dysfunction or liver dysfunction.  
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 to 4 tablets (50 to 100 mg of the active ingredient) per day in divided doses. The dosage may be adjusted according to the age or symptoms. Strictly follow the instructions.
- Urination at night may disturb your sleep. Take this medicine in the morning except when your doctor instructs you to take it at another time of day.
- 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. Nausea, vomiting, drowsy state, mental confusion, maculopapular rash, erythema, diarrhea, electrolyte imbalance (abnormal blood sodium, potassium and calcium levels) or dehydration may occur.
- Do not stop taking this medicine unless your doctor instructs you to do so.

## Precautions while taking this medicine

- Periodical electrolyte tests are performed, since continuous use of this medicine may cause electrolyte abnormality such as hyperkalemia.
- Dizziness or light headedness may occur associated with decreased blood pressure. Pay close attention when you drive a car, work at heights or operate dangerous machinery.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include gynecomastia, swelling of breasts, loss of sexual desire, impotence (male), excess hair, menstrual irregularity, loss of menstruation, genital bleeding after menopause, deepening of the voice, rash, hives, loss of appetite, nausea/vomiting, dry mouth, diarrhea, constipation, dull, 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, general dullness, lassitude [electrolyte abnormality (e.g. hyperkalemia, hyponatremia, metabolic acidosis)]
- decreased urine output, edema of limbs and face, headache [acute renal failure]
- rash, mucosal erosion/blister, high fever [toxic epidermal necrolysis, oculomucocutaneous 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 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 dispose of the unused medicines, 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.