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

Internal

Revised: 10/2019

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: CANDESARTAN TABLETS 4mg 「OHARA」 [hypertension]

Active ingredient: Candesartan cilexetil

Dosage form: white to yellowish white tablet, diameter: 7.1 mm, thickness: 2.6 mm

Print on wrapping:カンデサルタン 4mg「オーハラ」, 4mg, Candesartan4mg

「OHARA



Effects of this medicine

This medicine is antagonistic to angiotensin II receptor, a substance in the body which constricts blood vessels to elevate blood pressure. It lowers blood pressure by reducing the peripheral blood vascular resistance. It is usually used to treat hypertension.

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 high blood level of potassium, low blood level of sodium, cardiac disease, renal disorder, or liver disorder.

If you are in a preoperative condition, on hemodialysis, or on a regimen of low-salt diet.

- · If you are pregnant, possibly 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))
- <u>Hypertension (adults)</u>: In general, for adults, take 1 to 2 tablets (4 to 8 mg of the active ingredient) at a time, once a day. The dosage may be increased up to 3 tablets (12 mg) at a time, once a day as needed. If you have renal disorder, start with 0.5 tablet (2mg) at a time, once a day and the dosage may be increased up to 2 tablets (8 mg) at a time, once a day as needed.

<u>Hypertension (children)</u>: In general, for children aged 1 or over but under 6 years, take 0.05 to 0.3 mg of the active ingredient per kilogram of the body weight at a time, once a day. For children aged 6 years or over, take 0.5 to 2 tablets (2 to 8 mg of the active ingredient) at a time, once a day. The dosage may be increased up to 3 tablets (12 mg) at a time, once a day as needed. If you have renal disorder, start with low dose and the dosage may be increased up to 2 tablets (8 mg) at a time, once a day as needed.

<u>Renal parenchymal hypertension</u>: In general, for adults, start with 0.5 tables (2 mg of the active ingredient) at a time, once a day. The dosage may be increased up to 2 tablets (8 mg) at a time, once a day as needed. This preparation contains 4 mg of the active ingredient in a tablet. Strictly follow the instructions.

- •If you miss a dose, take the missed dose as soon as possible. However, wait at least 8 hours to take the next dose. 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

•Dizziness and light headedness may appear due to excessive lowering of blood pressure. Pay close attention when working at heights or operating dangerous machinery such as driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, eczema, hives, itching, photosensitivity, dizziness, light headedness, dizziness on standing up, palpitation, glow, headache, dull headache, insomnia, sleepiness, numbness of the tongue, nausea, vomiting, loss of appetite, gastric distress, pain in the pit of stomach, diarrhea, stomatitis, anemia, makaise, lassitude, nose bleeding, frequent urination, edema and cough. 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.

•swelling of face/tongue/throat, breathing difficulty [angioedema]

- •feeling cold, vomiting, loss of consciousness [shock, syncope, loss of consciousness]
- ·decreased urine output, edema of face/limbs, fever [acute renal disorder]
- •numbness of limbs/lips, muscle weakness [hyperkalemia]
- •yellowing of the skin and the white of eyes, dullness, loss of appetite [liver dysfunction, jaundice]
- •fever, sore throat, dullness [agranulocytosis]
- ·lassitude, muscle pain, brown urine [rhabdomyolysis]
- •fever, dry cough, breathing difficulty [interstitial pneumonia]
- •cold sweat, feeling hungry, trembling of hands [hypoglycemia]

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.

For healthcare professional use only

For further information, talk to your doctor or pharmacist.

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