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

Internal

Revised: 09/2025

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 12mg [OHARA]

Active ingredient: Candesartan cilexetil

Dosage form:light orange tablet, diameter: 7.1 mm, thickness: 2.6 mm **Imprint or print on wrapping:**カンデサルタン 12 mg「オーハラ」, 12 mg,

Candesartan 12 mg「OHARA」



Effects of this medicine

This medicine lowers blood pressure by reducing the peripheral vascular resistance through antagonistic effects on the receptors of angiotensin II, a substance in the body that constricts blood vessels and increases blood pressure. It is usually used to treat hypertension.

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 a high blood level of potassium, a low blood level of sodium, a cardiac disease, renal 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 4 to 8 mg of the active ingredient at a time, once a day. The dosage may be increased up to 12 mg at a time, once a day as needed. If you have renal disorder, start with 2 mg at a time, once a day. The dosage may be increased up to 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 2 to 8 mg of the active ingredient at a time, once a day. The dosage may be increased up to 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 8 mg at a time, once a day as needed.

<u>Renal parenchymal hypertension</u>: In general, for adults, start with 2 mg of the active ingredient at a time, once a day. The dosage may be increased up to 8 mg once a day as needed.

This medicine contains 12 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

- •Excessive lowering of blood pressure may result in dizziness and light headedness. Pay close attention when working at heights, or operating dangerous machinery, such as driving a car.
- This medicine cannot be used by pregnant and possible pregnant women. If you become pregnant or think you may be pregnant while taking this medicine, consult your doctor immediately.

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, malaise, 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, abdominal pain, diarrhea [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. 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

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For further information, talk to your doctor or pharmacist.

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