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

Internal

Revised: 02/2016

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: IMIDAPRIL HYDROCHLORIDE TABLETS 5mg[OHARA]

Active ingredient: Imidapril hydrochloride

Dosage form: white tablet with split line on one side, diameter: 7.0 mm, thick ness: 2.9

mm

Print on wrapping:(face) イミダプリル塩酸塩 5mg「オーハラ」, OH-214, 5

(back) Imidapril Hydrochloride 5mg「OHARA」, イミダプリル塩酸塩

「オーハラ」,5mg,高血圧症のお薬です



Effects of this medicine

This medicine enlarges the peripheral arteries by inhibiting angiotensin-converting enzyme and suppressing production of angiotensin II, and consequently decreases blood pressure. It also improves diabetic nephropathy by angiotensin-converting enzyme (ACE) activity in the kidney. It is usually used for the treatment of hypertension and renal parenchymal hypertension and diabetic nephropathy caused by type 1 diabetes mellitus.

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 a history of angioedema.
- · If you are receiving apheresis or hemodialysis.
- If you are a patient with renal artery stenosis, hyperkalemia, or cerebrovascular disorder.
- •If you are on a sodium restriction 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>>
- •Hypertension and renal parenchymal hypertension: In general, for adults, take 1 to 2 tablets (5 to 10 mg of the active ingredient) at a time, once daily. The dosage may be adjusted according to the diseases, age or symptoms, however, for patients with severe hypertension, accompanied by renal disorder, or renal parenchymal hypertension, the initial dose may be started with 1/2 tablet (2.5 mg) at a time. Diabetic nephropathy caused by type 1 diabetes mellitus: In general, for adults, take 1 tablet (5mg of the active ingredient) at a time, once daily. However, for patients with serious renal disorder, the initial dose may be started with 1/2 tablet (2.5 mg) at a time. Strictly follow the instructions of your doctor/pharmacist.
- •Take a dose as soon as possible when you remembered that you missed a dose. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. DO NOT take double doses to make up for the missed dose.
- ·If you took too much of the medicine (more than prescribed), check with your doctor/pharmacist.
- •Do not stop taking the medicine without the instructions of your doctor.

Precautions while taking this medicine

• The medicine may cause dizziness or lightheadedness due to the antihypertensive action. Pay close attention when you work at heights, drive a car or operate dangerous machinery.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include cough, hypotension, dizziness, headache, discomfort or uncomfortable feeling in the pharynx, lightheadedness, rash, etc. 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.

- •breathing difficulty, swelling of the face, tongue, or throat [angioedema]
- •nasal bleeding, gum bleeding, subcutaneous hemorrhage in the limbs [thrombocytopenia]
- general malaise, edema, thirst [acute renal failure, exacerbation of renal dysfunction]
- •numbness in the limbs or lips, decline in muscular strength, paralysis in the limbs [[hyperkalemia]
- •erythema, fever, enanthem [erythroderma, Stevens-Johnson syndrome, pemphigus-like symptoms]

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 the medicine out of the reach of children. Store it 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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