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

Internal

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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: ILUAMIX COMBINATION TABLETS HD TOHARAJ

Active ingredient:Irbesartan

Amlodipine besilate

Dosage form:light orange tablet, diameter: 8.2 mm, thickness: 3.8 mm

Print on wrapping:イルアミクス HD 配合錠「オーハラ」, イルベサルタン 100mg, アムロ

ジピン 10mg, 血圧降下薬,1日1回服用,ILUAMIX Combination Tab

HD OHARA I



Effects of this medicine

This medicine decreases blood pressure by competitively antagonizing against angiotensin II type 1 receptors, and by reducing calcium ion flow into cell and relaxing smooth muscle of peripheral vessels.

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 diabetes mellitus.
- · 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))
- •In general, for adults, take 1 tablet at a time, once a day. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. However, 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 this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- The medicine may cause dizziness or lightheadedness due to decreased blood pressure. Pay attention when working at heights, driving a car or operating dangerous machinery.
- •Do not take grapefruit juice with this medicine since it may intensify the medicinal effect of the medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dizziness, lightheadedness, edema, liver dysfunction, rash, itch, hives, photosensitivity (exaggerated sunburn caused by sunlight, itch, pigmentation), erythema multiforme, vasculitis, angioedema, and gum hyperplasia. 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 face, tongue or throat [angioedema]
- •weakness of the limbs, numbness of lips, muscle weakness [hyperkalemia]
- •vomiting, faint, loss of consciousness [shock, syncope, loss of consciousness]
- •edema, malaise, decreased urine output or anuria [renal failure]
- •general malaise, loss of appetite, yellowing of the skin and white of eyes [fulminant hepatitis, liver dysfunction, jaundice]

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 it at room temperature (1 to 30°C) direct sunlight and moisture.
- •Discard the remainder. Do not store them. Ask the pharmacist and the medical institution how to discard them.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.