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

Internal

Revised: 09/2018

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: OLMESARTAN OD TABLETS 20mg 「OHARA」

Active ingredient:Olmesartan medoxomil

Dosage form: white tablet, diameter: 8.0 mm, thickness: 2.5 mm

Print on wrapping: オルメサルタン OD20mg「オーハラ」,血圧降下薬,1 日 1 回服用,口

腔内崩壊錠, OlmesartanOD20mg「OHARA」



Effects of this medicine

This medicine exerts a selective action on angiotensin II type 1 receptor and competitively inhibits the binding of angiotensin II in order to decrease blood pressure.

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 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 10 to 20 mg of the active ingredient at a time, once a day. Start with 5 to 10 mg a day, then, the dose may be adjusted according to your age and symptoms. The maximum daily dose is 40 mg a day. This preparation contains 20 mg of the active ingredient in a tablet. Strictly follow the instructions.
- •Since the tablet dissolves in saliva when you place it on your tongue, you can take it without water. You can also take it with water.
- Do not take the tablet without water when you are lying down.
- •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

• This medicine may cause dizziness/light headedness due to its hypotensive action. Pay attention when working at heights, driving a car or operating dangerous machinery.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include itch and rash. 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.

- •respiratory distress, swelling of eyelids/lips/tongue, hives [angioedema]
- ·decreased urine output, edema, headache [renal failure]
- •numbness in the limbs/lips, muscular weakness, paralysis of limbs [hyperkalemia]
- •cold feeling, vomiting, loss of consciousness [shock, syncope, loss of consciousness]
- •general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]
- •nasal bleeding, gum bleeding, subcutaneous bleeding [decreased platelets]
- •sweating, palpitation, lassitude [hypoglycemia]
- •muscle pain, losing strength, reddish brown urine [rhabdomyolysis]
- •itch, generalized redness, decreased blood pressure [anaphylaxis]
- •nausea, severe stomachache, watery stool [severe diarrhea]

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.

SIE2