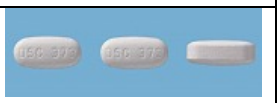
Drug Information Sheet("Kusuri-no-Shiori")

Internal
Revised: 07/2023

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:REZALTAS COMBINATION TABLETS HD



Active ingredient: Olmesartan medoxomil
Azelnidipine

Dosage form:one surface white, one surface white to yellowish white tablet (major axis: 14.2 mm, minor axis: 6.7 mm, thickness: approx. 5.3 mm)

Imprint or print on wrapping:レザルタス配合錠 HD，レザルタス HD, DSC373，オルメサルタンメドキソミル 20mg／アゼルニジピン 16mg, RezaltasHD，高血圧症のお薬です

Effects of this medicine

This medicine is a combination preparation of an angiotensin receptor blocker and a calcium antagonist. It lowers blood pressure by suppressing the vasoconstriction action of angiotensin II in vascular smooth muscles with angiotensin receptor blocker, and by dilating blood vessels with calcium antagonist.
It is usually used in the treatment of 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: renal artery stenosis, hyperkalemia, renal disorder, hepatic disorder, cerebrovascular disorder.
・If you are on hemodialysis, or on a strict 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))
・In general, for adults, take 1 tablet at a time, once a day after breakfast. Strictly follow the instructions.
The medicine contains 20 mg of olmesartan medoxomil and 16 mg of azelnidipine in 1 tablet.
・If you miss a dose, take the missed dose as soon as possible. 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 or lightheadedness by decreasing blood pressure. Pay attention when you work at heights, drive a car or operate dangerous machinery.
・Do not drink grapefruit juice while you take the medicine because it may cause an excessive hypotensive response by increasing blood level of the medicine.
・Prior to administration of this medicine, the absence of pregnancy should be confirmed. Also, during administration of this medicine, the absence of pregnancy should be confirmed periodically. If pregnancy is planned, detected or suspected, the attending doctor should be consulted immediately.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dizziness and headache. 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 in the eyelids/lips/tongue, hives [angioedema]
・decreased urine output, edema, headache　[renal failure]
・numbness of limbs or lips, muscle weakness, paralysis of arms/legs [hyperkalemia]
・cold feeling, vomiting, fainting, loss of consciousness [shock, syncope, loss of consciousness]
・general malaise, loss of appetite, yellowing in the skin/white of eyes　[liver dysfunction, jaundice]
・nasal bleeding, gums bleeding, subcutaneous bleeding　[thrombocytopenia]
・cold sweat, a sense of hunger, weakness [hypoglycemia]
・dizziness, lightheadedness　[atrioventricular block, sinus arrest, bradycardia]
・muscle pain, lassitude, red-brown urine　[rhabdomyolysis]

・itch, general redness, decreased blood pressure, decreased consciousness, palpitation [anaphylaxis]
・nausea, severe stomachache, watery stools [severe diarrhea]
・fever, dry cough, breathing difficulty, shortness of breath [interstitial pneumonia]

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 light, heat and moisture.
・Discard the remainder. Do not store them. If you do not know how to discard the remainder, ask your pharmacist or medical institution. Do not give the medicine to anyone else.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.