

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

Internal
Revised: 12/2022

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: EXFORGE Combination Tablets

Active ingredient: Valsartan

Amlodipine besilate

Dosage form: yellowish white tablet, diameter: 8.5 mm, thickness: 3.9 mm

Imprint or print on wrapping: エックスフォージ配合錠, EXFORGE, NV140



Effects of this medicine

This medicine blocks the vasoconstrictive effects of angiotensin II produced in the body, and dilates peripheral blood vessel to lower blood pressure in patients with hypertension.

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: diabetes mellitus, renal disorder, hepatic disorder, hyperkalemia or schedule of surgery.
If you are on dialysis or a regimen of low-salt diet.
- If you are pregnant or breastfeeding, possibly pregnant.
- 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 a dose as soon as possible. However, if it is 8 hours or less before 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 light-headedness since the blood pressure is decreased. Pay attention when you work at heights, drive a car or operate dangerous machinery.
- Avoid taking the medicine with grapefruit juice, as it may intensify the effect of the medicine.
- This medicine has been reported to be teratogenic (may cause malformations in fetuses), so if you suspect that you are pregnant, contact your doctor immediately.
- It is recommended not to breastfeed while taking this medicine. If you are breastfeeding, consult with your doctor.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dizziness 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.

- swelling of eyelids, lips and/or tongue, difficulty swallowing or breathing (due to edema of the airway) [angioedema]
- loss of appetite, general malaise, yellow discoloration of skin and/or conjunctiva [hepatitis fulminant, hepatitis, hepatic function disorder, jaundice]
- decrease of urine output, edema, loss of appetite [renal failure]
- numbness of limbs or lips, muscle weakness, paralysis of arms and/or legs [hyperkalemia]
- cold sweat, pale face, losing consciousness [shock, syncope, unconsciousness]

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 the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you are not sure how to discard, consult with your pharmacist or medical institution. Do not give it to anyone else.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.