

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

Internal

Revised: 08/2021

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:Forxiga 5mg tablets

Active ingredient:Dapagliflozin propylene glycolate hydrate

Dosage form:pale yellow to yellow round tablet, diameter: 7.1 mm, thickness: 3.2 mm

Imprint or print on wrapping:(Face)フォシーガ 5mg, フォシーガ, 5, (Back)forxiga5mg,
フォシーガ, 5, 1日1回服用, 1427



Effects of this medicine

This medicine improves plasma glucose levels by suppressing renal glucose reabsorption leading to urinary glucose excretion, and chronic heart failure or chronic kidney disease by adjusting the amount of fluid or various other actions.

It is usually used to treat type 1 and type 2 diabetes mellitus, chronic heart failure and chronic kidney disease.

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 (itching, rash, etc.) to any medicines or foods.
If you have: ketosis (nausea, sweet-sour breath, overbreathing), diabetic coma or precoma, infection, injury, pituitary insufficiency, adrenal insufficiency, urinary tract infection, genital infection, renal dysfunction or liver dysfunction.
- If you are in pre/postoperative period, malnourished, overly thin, starving or debilitated.
- If you have irregular eating habits or you cannot eat enough.
- If you exercise intensely or drink a lot of alcohol.
- 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))
- Type 2 diabetes mellitus: In general, for adults, take 1 tablet (5 mg of dapagliflozin) at a time, once a day. If the dose seems to be insufficient, it may be increased to 2 tablets (10 mg of dapagliflozin) at a time, once a day.
- Type 1 diabetes mellitus: In general, for adults, take 1 tablet (5 mg of dapagliflozin) at a time, once a day, in combination with insulin formulation. If the dose seems to be insufficient, it may be increased to 2 tablets (10 mg of dapagliflozin) at a time, once a day.
- Chronic heart failure, chronic kidney disease: In general, for adults, take 2 tablets (10 mg of dapagliflozin) at a time, once a day. If you also have type 1 diabetes mellitus, start at 1 tablet (5 mg of dapagliflozin) at a time, once a day. In any case, strictly follow the instructions.
- If you have type 1 diabetes mellitus, never discontinue insulin injection.
- 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 follow 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

- Strictly follow the instructions on dietary/exercise therapy. This medicine may cause hypoglycemia symptoms (low blood sugar) (e.g. light headedness, lassitude, cold sweat, palpitation, shivering of limbs). Pay close attention when you perform any operations with potential risk such as working at heights or driving a car. You should inform your family and persons around you about the risk of low blood sugar. If any symptoms of low blood sugar occur, consume sugar or sugar-rich foods immediately. If you are taking α -glucosidase inhibitor (acarbose, voglibose and miglitol) concomitantly, take glucose.
- This medicine may cause dehydration symptoms (e.g. change in urine output, thirst, lassitude, dizziness, dry skin) because it increases your urine output. To prevent dehydration, drink water frequently while taking this medicine even if you do not feel thirsty. You should not stop drinking water without consultation with your doctor. If dehydration symptoms occur or water intake seems to be insufficient (e.g. in case of illness or detecting/appealing of thirst may be difficult due to dementia), consult with your doctor or pharmacist.
- If the following symptoms occur (when you are sick), consult with your doctor immediately and follow his/her instructions before taking the next dose: fever, diarrhea/vomiting, loss of appetite or you cannot eat enough.
- Because of excessive glucose excreted with urine, this medicine may cause urinary tract infection (e.g. frequent

urination, feeling of residual urine, pain during urination) and/or genital infection (e.g. genital itching and pain). It may lead to pyelonephritis and necrotizing fasciitis, known as Fournier's gangrene, of vulva and perineal region and finally to sepsis. If such symptoms occur, consult with your doctor immediately.

- Because of excessive glucose excreted with urine, this medicine may cause ketoacidosis (blood becomes acidic) without significant rise in blood glucose levels. If the following symptoms occur, consult with your doctor immediately before taking the next dose: nausea, vomiting, loss of appetite, abdominal pain, severe thirst, malaise, overbreathing or decreased consciousness. The following patients should pay attention because they may easily fall into ketoacidosis: patients with type 1 diabetes mellitus or decreased insulin secretion, who stopped or reduced insulin formulation, who are subject to excessive carbohydrate intake restriction, who cannot eat or with infection or dehydration. If you have type 1 diabetes mellitus, never discontinue insulin injection.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include genital infection (vaginal candidiasis, etc.), urinary tract infection (cystitis, etc.), decreased body fluid (dehydration), constipation, thirst, frequent urination, increased urine output and genital itching. 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.

- light headedness, lassitude, cold sweat, palpitation, shivering of limbs [hypoglycemia]
- chills, fever/high fever, flank pain, back pain, joint/muscle pain [pyelonephritis/necrotizing fasciitis (Fournier's gangrene) of vulva and perineal region/sepsis]
- change in urine output, thirst, general dullness, lassitude, dizziness, dry skin [dehydration]
- nausea, vomiting, loss of appetite, abdominal pain, severe thirst, malaise, overbreathing, decreased consciousness [ketoacidosis]

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 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.