

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

Internal

Revised: 03/2019

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: SUJANU Combination Tablets

Active ingredient: Sitagliptin phosphate hydrate

Ipragliflozin L-Proline

Dosage form: pale yellowish red tablet, diameter: 9.6 mm, thickness: 4.6 mm

Imprint or print on wrapping: スージャヌ配合錠, シタグリプチン 50mg, イブラグリフロジン 50mg, SUJANU 配合錠, 糖尿病用薬, 1 日 1 回服用



Effects of this medicine

This medicine inhibits enzyme that degrades incretin, blood glucose stabilizing substance, and enhances insulinotropic action and effect of lowering glucagon level in state of hyperglycemia. It also inhibits SGLT2 that resorbs glucose in the kidney to excrete excess glucose into urine. These actions consequently improve blood glucose control.

It is usually used to treat type 2 diabetes.

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: ketosis, diabetic coma or precoma stage, type 1 diabetes, infection, injury, renal dysfunction, liver dysfunction, pituitary gland disorder, adrenal gland disorder, irregular meals, insufficient diet, urinary tract/genital infection or a history of abdominal surgery or intestinal obstruction.
- If you are in pre/postoperative period; are in a state of poor nutrition or starvation; are extremely underweight or debilitated.
- If you do intense muscular exercise 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))
- In general, for adults, take 1 tablet at a time, once a day before or after breakfast. Strictly follow the instructions.
- If you miss a dose, skip the missed dose and take a dose next morning. 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.
- In case hypoglycemic symptoms occur, take food or drink that contains enough amount of sugar (sugar, glucose, refreshing drink, etc.). If you are taking this medicine concomitantly with an alpha-glucosidase inhibitor (medicines which delay absorption of sugar), ingest glucose in case of any hypoglycemic symptoms occur.
- This medicine may cause hypoglycemic symptoms. Pay attention when you work at heights, drive a car or operate dangerous machinery.
- Take a larger amount of water, since this medicine may cause dehydration. Intake of water or tea is desirable, since drink including sugar such as isotonic drink may increase blood glucose.
- Do not stop taking water or decrease the amount of water on your own judgment.
- Stop taking this medicine if you have repeated diarrhea/vomiting or cannot take food or water continuously due to decreased appetite.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include frequent urination, dry mouth and constipation. 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.

- chills, a sense of hunger, shivering of limbs [hypoglycemia]
- severe upper abdominal pain, lumbar/back pain, nausea [acute pancreatitis]
- blister, erosion, erythema [pemphigoid]
- chills, fever, flank/back pain [pyelonephritis, sepsis]

- thirst/dry mouth, large urinary volume, dizziness/light headedness [dehydration]

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.