

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

Internal

Revised: 01/2020

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: Suglat Tablets 25mg

Active ingredient: Ipragliflozin L-proline

Dosage form: pale yellow tablet, diameter: approx. 8.1 mm, thickness: approx. 3.6 mm

Print on wrapping: (face) スーグラ 25mg, スーグラ, 25mg, 糖尿病の薬, アステラス製薬, (back) Suglat 25mg, スーグラ, 25, 糖尿病の薬, company mark, アステラス製薬



Effects of this medicine

This medicine inhibits SGLT2 which resorbs glucose in the kidney, thus reducing blood glucose through the excretion of excess glucose into urine.

It is usually used for the treatment of type 1 diabetes or type 2 diabetes.

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 have: ketosis (nausea, sweet and sour smelling breath, deep and big breaths), infections, injury, pituitary gland dysfunction, abnormal adrenal gland function, irregular meals, inadequate food intake, urinary tract infection, genital infection or liver dysfunction.
- If you are in a diabetic coma or a precoma stage; are perioperative, extremely underweight; are in a state of poor nutrition or starvation; are debilitated, a heavy drinker; are doing intense muscular exercise.
- If you have renal dysfunction or are on dialysis.
- 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: In general, for adults, take 2 tablets (50 mg of ipragliflozin) at a time, once a day before or after breakfast. If the effect of this medicine is insufficient, it may be increased up to 4 tablets (100 mg) once a day while carefully following the course of the disease.
- Type 1 diabetes: In general, for adults with insulin preparation, take 2 tablets (50 mg of ipragliflozin) at a time, once a day before or after breakfast. If the effect of this medicine is insufficient, it may be increased up to 4 tablets (100 mg) once a day while carefully following the course of the disease.
- In any case, if you have a severe hepatic dysfunction, the dosage may be started with low doses. Strictly follow the instructions.
- If you miss a 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 hypoglycemic symptoms. Pay close attention when working at heights or operating dangerous machinery such as driving a car.
- Take foods containing sugar or drink juice if any hypoglycemic symptoms occur. If you are taking in conjunction with α -glucosidase inhibitors (medicines which delay the uptake of glucose) and hypoglycemic symptoms develop, you must take in glucose.
- This medicine may cause ketosis although your blood glucose level is nearly normal. The following patients should pay attention because they may easily fall into ketoacidosis: patients with type 1 diabetes mellitus, who reduced or stopped insulin formulation, who are subject to excessive carbohydrate intake restriction, who cannot eat sufficiently or with infection or dehydration. If you have type 1 diabetes mellitus, do not discontinue insulin injection.
- Take a larger amount of water, since this medicine may cause dehydration. Do not stop taking water or decrease the amount of water on your own judgment.
- Stop taking the 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, excessive urination, constipation, dry mouth, weight loss, cystitis and genital pruritus (itch). 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, sweating, a sense of hunger, shivering of limbs [hypoglycemia]
- chills, fever, flank pain, back pain, lower back pain, redness/swelling/pain in the genital area [pyelonephritis, necrotizing fasciitis of the vulva and perineum (Fournier’s gangrene), sepsis]
- thirst/dry mouth, excessive urination, dizziness/light headedness [dehydration]
- nausea/vomiting, loss of appetite, abdominal pain, severe dry mouth, malaise [ketoacidosis]
- facial pallor, cold sweat, dizziness on standing up [shock, anaphylaxis]

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.