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

Internal Revised: 10/2022

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:**SG Combination Granules

Active ingredient: Isopropylantipyrine

Acetaminophen Allylisopropylacetylurea Anhydrous caffeine

Dosage form: white granules

Imprint or print on wrapping:SG 配合顆粒 1g

#### Effects of this medicine

This medicine is an antipyretic analysis drug which contains four active ingredients including a pyrazolone drug. It is usually used to reduce a fever associated with a cold and to relieve earache, sore throat, menstrual pain, headache, toothache, neuralgia, pain from injury, etc.

## 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 aspirin-induced asthma or its history, or hepatic function disorder.
- ·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 g or 1 sachet (1 g) at a time, 3 or 4 times a day.
- In case of a use as needed (for high fever or severe pain), for adults, take 1 to 2 g or 1 to 2 sachets (1 to 2 g) at a time. An additional dose should be taken after a dosing interval of at least four hours.
- In both cases, the dosage may be adjusted according to your disease, age and symptoms. However, the total daily dose should be up to 4 g or 4 sachets (4 g). Strictly follow the instructions.
- •If you miss a dose, take the missed dose as soon as possible. If it is close to your next dose, skip the missed dose. 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

- •Since this medicine may induce drowsiness or lack of attentiveness and concentration, do not drive a car or operate dangerous machinery as far as possible.
- ·Alcohol may induce or enhance the adverse reactions of this medicine.

#### Possible adverse reactions to this medicine

The most commonly reported adverse reactions include sleepiness, stomach discomfort, malaise, rash, erythema, itch and renal dysfunction (decreased urinary volume, swelling). 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.

- •bleeding tendency, general malaise, yellowness in skin or in the white of eyes [thrombocytopenia, hemolytic anemia]
- •fever, fluid-filled blister, inflammation in mucous membrane of eyes, mouth, etc., general redness [toxic epidermal necrolysis, mucocutaneous ocular syndrome, acute generalized exanthematous pustulosis]
- ·cold sweat, dizziness, generalized itching [shock, anaphylaxis]
- •cough, breathlessness, fever [interstitial pneumonia]
- •yellowness in skin or in the white of eyes, malaise, loss of appetite [fulminant hepatitis, hepatic function disorder, jaundice]

## 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 the medicine out of the reach of infants and children. Store it at room temperature (1 to 30 degrees Celsius)



away from direct sunlight and moisture.

•Discard the remainder. Do not store them. If you do not know how to discard, consult your pharmacy or medical institution about how to discard them. Do not give this medicine to anyone else.

For healthcare professional use only /

For further information, talk to your doctor or pharmacist.