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

Internal Revised: 04/2019

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: Solantal Tablets 100mg

Active ingredient: Tiaramide hydrochloride

Dosage form:white tablet (diameter: 7.1mm, thickness 3.1mm)

Imprint or print on wrapping: New (Face) ソランタール 100mg, LT001, (Back) ソランタ

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Old (Face) ソランタール 100mg, f311, (Back) ソランタール 100, チ

アラミド (Tiaramide)



Effects of this medicine

This medicine opposes the chemical substances such as histamine and serotonin at the inflamed site and shows specifically acute anti-inflammatory effect.

It is usually used to relieve pain and inflammation of the post-operative wound, arthritis, post-tooth extraction wound, acute upper respiratory inflammation, 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: peptic ulcer, blood abnormality, liver disorder, renal disorder or a past history of aspirin asthma.
- · 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))
- For other conditions than pain due to acute upper respiratory tract infection: In general, for adults, take 1 tablet (100 mg of tiaramide) at a time, 3 times daily. The dosage may be adjusted according to the patients age and symptoms.

For pain due to acute upper respiratory tract infection: In general, for adults, take 1 tablet (100 mg) at a time, on an as-needed basis. The dosage may be adjusted according to the patients age and symptoms. However, as a general rule, this medicine should not be taken more than twice a day, and the maximum daily dose should not exceed 3 tablets (300 mg).

Strictly follow the instructions.

- If you miss a dose, take the missed dose as soon as possible. However, if it is almost time for 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.
- $\bullet \mbox{Do}$ not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, loss of appetite, nausea, heartburn, abdomen enlarged feeling and abdominal pain. 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.

- •facial pallor, cold sweat, dizziness on standing up [shock]
- difficulty with breathing, hives, swelling around the eyes or lips [anaphylactoid symptoms]

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 the reach of infants and children. Store away from direct sunlight, heat and humidity.
- ·Discard the remainder. Do not store them.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.