

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

Internal

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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: Calonal Tablet 300

**Active ingredient:** Acetaminophen

**Dosage form:** white tablet, diameter: 10.0 mm, thickness: 4.0 mm

**Print on wrapping:** (Face) 300mg, アセトアミノフェン, カロナール, SD113, (Back) カロナール, 300mg, 解熱鎮痛剤



## Effects of this medicine

This medicine shows antipyretic and analgesic effects by acting on central nerve. It also lowers fever by directly acting to the temperature-regulating center and increasing heat dissipation.

It is usually used for pain relief (headache, low back pain, toothache, osteoarthritis, etc.), treatment of acute upper respiratory inflammation, and relief of fever and pain associated with pediatric diseases.

## 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: peptic ulcer, blood disease, liver disorder, kidney disorder, heart dysfunction, aspirin-induced asthma or its history.
- 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 pain relief (headache, low back pain, toothache, osteoarthritis, etc.): In general, for adults, take 300 to 1,000 mg of the active ingredient at a time. The dosage interval should be longer than 4 to 6 hours. The maximum daily dose is up to 4,000 mg. Avoid taking this medicine on an empty stomach.  
For antipyresis and pain relief in acute upper respiratory inflammation: In general, for adults, take 300 to 500 mg of the active ingredient at a time as needed. As a rule, up to twice a day and the maximum daily dose is up to 1,500 mg. Avoid taking this medicine on an empty stomach.  
For antipyresis and pain relief in pediatric diseases: In general, for infants and children, take 10 to 15 mg of the active ingredient per kilogram of the body weight at a time. The dosage interval should be longer than 4 to 6 hours. The maximum daily dose is up to 60 mg per kilogram of the body weight. However, the dosage should not exceed the adult dosage (the maximum single dose is up to 500 mg and the maximum daily dose is up to 1,500 mg). Avoid taking this medicine on an empty stomach.  
In any case, the dosage may be adjusted according to the disease, age or symptoms. This preparation contains 300 mg of the active ingredient in a tablet. 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 (no more than 4 hours), 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

- Do not take other medicines containing acetaminophen (OTC cold remedy, etc.) while taking this medicine. Liver dysfunction may occur because of acetaminophen overdose.
- If long-term administration is performed at a high dose beyond a total daily dose of 1,500 mg, liver function test is regularly conducted. Conduct liver function test at the designated time and date.
- Refrain from drinking alcohol while taking this medicine. Alcohol makes adverse reactions more likely to occur.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include hypersensitivity (eruption), vomiting, loss of appetite and decrease of platelet function (prolongation of bleeding time). 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.**

- breathing difficulty, generalized flushing, hives [shock, anaphylaxis]
- high fever, eruptions or blisters on skin or mucosa, bloodshot eyes [toxic epidermal necrolysis, Stevens-Johnson]

syndrome, and acute generalized exanthematous pustulosis]

- breathing difficulty, wheezing (whistling sound) [induction of asthma attacks]
- malaise, loss of appetite, yellowing in skin and white of eyes [fulminant hepatitis, liver dysfunction, jaundice]
- sore throat, fever [granulocytopenia]
- breathing difficulty, cough, fever [interstitial pneumonia]
- fever, rash, joint pain [interstitial nephritis, acute renal failure]

**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 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.