

# 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:** Panaldine Fine Granule 10%

**Active ingredient:** Ticlopidine hydrochloride

**Dosage form:** white to faintly yellowish white fine granule

**Imprint or print on wrapping:**



## Effects of this medicine

This medicine suppresses action of platelets in blood, and makes thrombus less likely to occur in blood vessels, thereby preventing recurrence of thrombosis and blood flow disturbance.

It is usually used to treat thrombus/embolus and improve blood flow disturbance.

## 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 bleeding (hemophilia, capillary fragility, gastrointestinal ulcer, urinary tract bleeding, hemoptysis, vitreous bleeding, etc.), liver disorder, leukopenia, a schedule for surgery (including tooth extraction), or hypertension.
- 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 treatment of thrombus/embolus accompanied with vascular surgery or extracorporeal circulation and improvement of blood flow disturbance : In general, for adults, take 2 to 3 g (200 to 300 mg of the active ingredient) a day, in 2 to 3 divided doses, after meals.
  - For improvement of ischemic symptoms such as ulcer, pain or chills accompanied with chronic arterial occlusion : In general, for adults, take 3 to 6 g (300 to 600 mg of the active ingredient) a day, in 2 to 3 divided doses, after meals.
  - For treatment of thrombus/embolus accompanied with ischemic cerebrovascular disorder : In general, for adults, take 2 to 3 g (200 to 300 mg of the active ingredient) a day, in 2 to 3 divided doses, after meals. In case of taking 2 g (200 mg) a day, you may take it at once, once a day.
  - For improvement of blood flow disturbance accompanied with cerebral vasospasm after subarachnoid hemorrhage surgery : In general, for adults, take 3 g (300 mg of the active ingredient) a day, in 3 divided doses, after meals.
- The dosage may be adjusted according to your age and symptoms in any case. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as you remember. However, if it is almost time for the 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

- For the first 2 months from the start of taking this medicine, regular tests are needed for early detection of serious adverse reactions. Keep appointments with your doctor once every 2 weeks in principle. After 2 months, blood test should be performed on a regular basis.
- In case of bleeding, blood may not stop quickly. If bleeding time is prolonged or the injury involves a large area, immediately visit the nearest hospital.
- If you receive any treatment by another doctor, including dental treatment, make sure to tell the doctor or dentist that you are taking this medicine.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nasal bleeding, subcutaneous bleeding, rash, itch, fever, loss of appetite, nausea and headache. 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 (gum bleeding, nasal bleeding, subcutaneous bleeding), fever, purpura [thrombotic thrombocytopenic purpura]
- fever, sore throat, general malaise [agranulocytosis]
- yellow discoloration of skin/conjunctiva, general malaise, loss of appetite [serious liver disorder]

- palpitation and shortness of breath when going up stairs or a slope, general malaise, bleeding tendency, purpura [blood disorder such as pancytopenia including aplastic anemia, pure red-cell aplasia and thrombocytopenia]
- headache, consciousness disorder, abdominal pain, vomiting of blood, bloody stool [intracranial bleeding such as brain bleeding, serious bleeding such as gastrointestinal bleeding]

**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. If you do not know how to discard, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

**For healthcare professional use only**        /        /

For further information, talk to your doctor or pharmacist.