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

Internal

Published: 10/2007

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:Acinon Tablets 75mg

Active ingredient: Nizatidine

Dosage form: white to faintly yellowish white tablet (ϕ : 6.7mm, thickness: 3.3mm)

Imprint or print on wrapping:アシノン錠 75mg ZP45

Effects of this medicine

This antiulcer medicine blocks histamine H₂ receptor and inhibits gastric acid secretion. It is usually used to treat gastric/duodenal ulcer, esophageal inflammation, acute gastritis, and acutely exacerbated chronic gastritis.

The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.

•If you ever experienced any allergic reaction (itch, rash etc.) to any medicines or foods.

If you are a patient with hepatopathy or renal damage.

- •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))

•General dosage regimen: For the treatment of gastric/duodenal ulcer: For adults, take 2 tablets (150mg of the active ingredient) at a time, twice a day, after breakfast and at bedtime. Alternatively, 4 tablets (300mg) can be taken once a day at bedtime.

<u>For the treatment of reflux esophagitis</u>: For adults, take 2 tablets (150mg of the active ingredient) at a time, twice a day, after breakfast and at bedtime.

For the treatment of acute gastritis and acutely exacerbated chronic gastritis: For adults, take 1 tablet (75mg of the active ingredient) twice a day, after breakfast and at bedtime.

The dose may be adjusted according to your age and symptoms. Strictly follow the instructions of your doctor/pharmacist in any case.

- 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. DO NOT take a double dose to make up for the missed dose.
- If you took too much of this medicine (more than ordered), check with your doctor/pharmacist.
- •Do not stop taking this medicine without the instructions of your doctor.

Precautions while taking this medicine

Possible adverse reactions to this medicine

Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: rash/exanthem, constipation, diarrhea, hives, itch, anemia, gynaecomastia (for male patients), fever, facial edema, lactation.

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.

- ·hives, decreased blood pressure, breathing difficulty [shock, anaphylactoid symptoms]
- •generalized fatigability, fever, nose/gum bleeding [aplastic anemia, pancytopenia, agranulocytosis, thrombocytopenia]
- ·lassitude, loss of appetite, yellowness in the skin and the white of the eye [liver dysfunction, 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 out of the reach of children. Store away from heat, moisture and direct sunlight.
- •Discard the remainder. Do not store them.

For healthcare professional use only

/ /

For further information, talk to your doctor or pharmacist.