

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

Internal

Revised: 05/2016

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:** NIZATIDINE CAPSULES 75mg 「OHARA」

**Active ingredient:** Nizatidine

**Dosage form:** pale bluish green opaque and white opaque capsule, whole length: 14.2 mm, outside diameter: 5.1 mm

**Print on wrapping:** ニザチジン 75 mg 「オーハラ」, OH-336, 75 mg, Nizatidine 75 mg 「OHARA」



**Effects of this medicine**

This medicine blocks histamine H<sub>2</sub> receptors on gastric cell wall and suppresses secretion of gastric acid. It is usually used to treat gastric/duodenal ulcer and reflux esophagitis.

**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 renal or liver 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>>
- For gastric/duodenal ulcer: In general, for adults, take 2 capsules (150 mg of the active ingredient) at a time, twice a day, after breakfast and before bedtime. You may also take 4 capsules (300 mg) at a time, once a day, before bedtime.
- For reflux esophagitis: In general, for adults, take 2 capsules (150 mg of the active ingredient) at a time, twice a day, after breakfast and before bedtime.
- In any case, the dosage may be adjusted according to the disease, age or symptoms. Strictly follow the instructions.
- For improvement of gastric mucosal lesion (erosion, bleeding, redness and edema) in acute gastritis and in acute exacerbation period of chronic gastritis: In general, for adults, take 1 capsule (75mg of the active ingredient) at a time, twice a day, after breakfast and before bedtime.
- 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 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 using 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, hives, itch, anemia, constipation, diarrhea, gynecomastia, fever, facial edema and lactation. 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.**

- hives, dizziness/dizziness on standing up, respiratory distress [shock, anaphylactoid symptoms]
- general malaise, fever, bleeding tendency [aplastic anemia, pancytopenia, agranulocytosis, decreased platelets]
- general malaise, loss of appetite, yellow discoloration of the skin or the white of the eyes [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 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.

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