

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

Internal

Revised: 11/2013

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:**RABEPRAZOLE Na TABLETS 20mg 「OHARA」

**Active ingredient:**Sodium rabeprazole

**Dosage form:**pale yellow tablet, diameter: 7.3 mm, thickness: 3.7 mm

**Print on wrapping:**ラベプラゾール Na 塩 20mg「オーハラ」, ラベプラゾール, 20mg, プロトンポンプ阻害剤, Rabeprazole Na 20mg「OHARA」



## Effects of this medicine

This medicine inhibits an enzyme on the gastric wall cell and suppresses the gastric-acid secretion. It is usually used to treat gastric ulcer, 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 hepatic 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 ulcer, duodenal ulcer, anastomotic ulcer and Zollinger-Ellison syndrome: In general, for adults, take 10 mg of the active ingredient at a time, once a day. The dosage may be increased to 20 mg, once a day according to the symptoms. This medicine contains 20 g of the active ingredient in a tablet. The maximum duration of taking the medicine is 8 weeks for gastric ulcer and anastomotic ulcer, and 6 weeks for duodenal ulcer.  
For reflux esophagitis: In general, for adults, take 10 mg of the active ingredient at a time, once a day. The dosage may be increased to 20 mg, once a day according to the symptoms. The maximum duration of taking the medicine is 8 weeks. This medicine contains 20 g of the active ingredient in a tablet. When proton inhibitor treatment is ineffective, take 10 mg or 20 mg twice a day for further 8 weeks. However, a dose of 20 mg twice a day is only used in patients with severe mucosal injury.  
Strictly follow the instructions in any case.
- This medicine is an enteric coated tablet. Swallow the tablet without chewing or crushing.
- If you miss a dose, take a dose as soon as you remember. 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 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, itching, hives, constipation, diarrhea, abdominal bloating, nausea, headache and anemia (palpitation, shortness of breath and headache when going upstairs or uphill). 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, respiratory distress, hives [shock, anaphylaxis]
- general malaise, subcutaneous/submucosal bleeding, fever [pancytopenia, agranulocytosis, thrombocytopenia, hemolytic anemia]
- general malaise, loss of appetite, yellowing of the skin or white of the eye [severe hepatitis, hepatic dysfunction, jaundice]
- fever, dry cough, respiratory distress [interstitial pneumonia]
- widespread red rash, fever, mucosal erosion in the mouth or eye [toxic epidermal necrosis, mucocutaneous ocular syndrome, erythema multiforme]

**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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