

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

Internal

Revised: 06/2020

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 10mg 「OHARA」

Active ingredient:Rabeprazole sodium

Dosage form:pale yellow tablet (diameter: 6.9 mm, thickness: 3.6 mm)

Print on wrapping:ラベプラゾール Na 塩 10mg「オーハラ」, 10mg, プロトンポンプ阻害剤, Rabeprazole Na 10mg「OHARA」



Effects of this medicine

This medicine inhibits an enzyme on the parietal cell of the stomach and suppresses the secretion of stomach acid.

It is usually used to treat gastric ulcer, duodenal ulcer, reflux esophagitis, non-erosive gastroesophageal reflux disease, etc., or to help to eradicate *Helicobacter pylori* bacteria.

It is also used for suppression of recurrence of gastric/duodenal ulcer associated with low-dose aspirin medication.

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 treatment of gastric ulcer, duodenal ulcer, anastomotic ulcer or Zollinger-Ellison syndrome: In general, for adults, take 1 tablet (10 mg of the active ingredient) at a time, once a day. It may be increased to 2 tablets (20 mg) at a time, once a day according to the symptoms. The maximum duration of use is 8 weeks for gastric ulcer or anastomotic ulcer, and 6 weeks for duodenal ulcer.
For treatment of reflux esophagitis: In general, for adults, take 1 tablet (10 mg of the active ingredient) at a time, once a day. It may be increased to 2 tablets (20 mg) once a day according to the symptoms. The maximum duration of use is 8 weeks. When proton pump inhibitor treatment is ineffective, take 1 tablet (10 mg) or 2 tablets (20 mg) at a time, twice a day for further 8 weeks. However, a dose of 20 mg at a time twice a day is only used in patients with severe mucosa injury.
(Maintenance therapy) For reflux esophagitis that relapse/worsen repeatedly, take 10 mg at a time, once a day. When proton-pump inhibitor treatment is ineffective, take 10 mg at a time, twice a day as maintenance therapy.
- For treatment of non-erosive gastroesophageal reflux disease: In general, for adults, take 1 tablet (10 mg of the active ingredient) at a time, once a day. The maximum duration of use is 4 weeks.
- For suppression of recurrence of gastric/duodenal ulcer associated with low-dose aspirin medication: In general, for adults, take 5 mg of the active ingredient at a time, once a day. If the treatment is ineffective, take 10 mg at a time, once a day.
- For helping to eradicate *Helicobacter pylori* bacteria: In general, for adults, take 1 tablet (10mg of the active ingredient) concomitantly with 750 mg (titer) of amoxicillin hydrate and 200 mg (titer) of clarithromycin at a time twice a day for 7 days. Clarithromycin may be increased to 400 mg (titer) at a time, up to twice a day. If this treatment resulted in failure, take 1 tablet (10 mg) concomitantly with 750 mg (titer) of amoxicillin and 250 mg of metronidazole, at a time, twice a day, for 7 days.
Strictly follow the instructions in any case.
- Swallow the medicine without chewing or cracking as it is enteric coated tablet.
- If you miss a dose, take a dose as soon as possible when you remember that you missed a dose. However, if it is almost time for the next dose, skip the missed dose and continue 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, itch, hives, constipation, diarrhea, enlarged feeling of abdomen, nausea, headache and anemia (palpitation, shortness of breath, headache when climbing stairs or slope). 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.

- pale face, 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 and white of the eye [fulminant hepatitis, liver dysfunction, jaundice]
- fever, dry cough, respiratory distress [interstitial pneumonia]
- red rash appearing in vast area, fever, erosion in mouth/eye mucosa [toxic epidermal necrolysis, Stevens-Johnson 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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