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

Internal

Revised: 09/2017

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:Pariet Tablets 10mg

Active ingredient:Rabeprazole sodium

Dosage form: pale yellow tablet (diameter: 6.7 mm, thickness: 3.6 mm)

Print on wrapping:(Face) パリエット 10mg (Back) パリエット, 10, Pariet



Effects of this medicine

This medicine inhibits the mechanism of gastric acid secretion in gastric mucosal cells to suppress gastric acid secretion. It consequently results in rapid healing of gastric and duodenal ulcer, and relieves pain and heartburn attributed to reflux esophagitis.

It is usually used in the treatment of gastric ulcer, duodenal ulcer, reflux esophagitis, etc, and for helping 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 liver problems.
- · 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 daily. The dosage may be increased up to 20 mg, once daily. Duration of taking the medicine is up to 8 weeks for gastric ulcer and anastomotic ulcer; 6 weeks for duodenal ulcer.

For reflux esophagitis: (Treatment) 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 at a time, once a day according to your symptoms. The maximum duration of medication is 8 weeks. When proton-pump inhibitor treatment is ineffective, take 10 mg or 20 mg at a time, twice a day for another 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 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 daily. If the treatment is ineffective, take 10 mg at a time, once daily.

<u>For helping to eradicate Helicobacter pylori bacteria</u>: In general, for adults, take 10 mg of the active ingredient, at a time, twice daily, for 7 days, concomitantly with amoxicillin hydrate and clarithromycin. If this treatment resulted in failure, take 10 mg at a time, twice daily, for 7 days, concomitantly with amoxicillin hydrate and metronidazole. This medicine contains the main component 10 mg in one tablet.

Strictly follow the instructions in any case.

- Swallow the tablet without chewing or crushing.
- •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, hives, itching sensation, diarrhea, loose stool, taste abnormality, abdominal pain, abdominal bloating and constipation. 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.

•breathing difficulty, hives, dizziness [shock, anaphylaxis]

- •fever, anemia, gum bleeding, subcutaneous bleeding [pancytopenia, agranulocytosis, thrombocytopenia, hemolytic anemia]
- •general malaise, decreased appetite, yellowing in the skin or white of the eye [fulminant hepatitis, hepatic dysfunction, jaundice]
- •fever, dry cough, breathing difficulty [interstitial pneumonia]
- •fever, widespread red rash, erosion in the eye, mouth or genitalia [toxic epidermal necrosis, Stevens-Johnson syndrome, erythema multiforme]
- •decreased urine output, edema, fever [acute kidney injury, interstitial nephritis]
- •nausea, vomiting, convulsion, headache, impaired consciousness [hyponatremia]
- •muscular pain, weakness, reddish brown urine [rhabdomyolysis]

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 the medicine out of the reach of children. Store it away from direct sunlight, heat and moisture.
- ·Discard the remainder. Do not store them.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.