

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

Internal

Revised: 01/2018

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: Nexium Capsules 10

Active ingredient: Esomeprazole magnesium hydrate

Dosage form: grayish purple/light yellow capsule, major axis: 11.40 mm, minor axis: 4.90 mm

Print on wrapping: (Face) ネキシウム 10, (Back) Nexium 10, ネキシウム 10mg, 胃酸を抑える薬



Effects of this medicine

This medicine acts on a terminal step in gastric acid secretion, called proton-pump, and inhibits gastric acid secretion. It consequently increases pH in the stomach and enhances antimicrobial actions of antibacterial agents. It is usually used to treat gastric/duodenal/anastomotic ulcer, reflux esophagitis, non-erosive gastroesophageal reflux disease, Zollinger-Ellison syndrome, and for suppression of recurrence of gastric/duodenal ulcer associated with nonsteroidal anti-inflammatory drug or low-dose aspirin medication. Also, this medicine is used to help the eradication of Helicobacter pylori in the stomach in gastric/duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, after endoscopic therapy for early gastric cancer and Helicobacter pylori gastritis together with 2 other antibacterial agents.

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 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))
- To treat gastric/duodenal/anastomotic ulcer or Zollinger-Ellison syndrome: In general, for adults, take 2 capsules (20 mg of esomeprazole) at a time, once a day. The usual duration of administration is up to 8 weeks for gastric/anastomotic ulcer, and up to 6 weeks for duodenal ulcer.
In general, for children aged 1 year or over whose body weight is less than 20 kg, take 1 capsule (10 mg of esomeprazole) at a time, once a day. For children aged 1 year or over whose body weight is 20 kg or over, take 1 to 2 capsules (10 to 20 mg of esomeprazole) at a time, once a day, according to the symptoms. The usual duration of administration is up to 8 weeks for gastric/anastomotic ulcer, and up to 6 weeks for duodenal ulcer.
To treat reflux esophagitis: In general, for adults, take 2 capsules (20 mg of esomeprazole) at a time, once a day. The usual duration of administration is up to 8 weeks. For maintenance therapy of repeatedly recurrent/relapsing reflux esophagitis, take 1 to 2 capsules (10 to 20 mg of esomeprazole) at a time, once a day.
In general, for children aged 1 year or over whose body weight is less than 20 kg, take 1 capsule (10 mg of esomeprazole) at a time, once a day. For children aged 1 year or over whose body weight is 20 kg or over, take 1 to 2 capsules (10 to 20 mg of esomeprazole) at a time, once a day, according to the symptoms. The usual duration of administration is up to 8 weeks.
To treat non-erosive gastroesophageal reflux disease: In general, for adults, take 1 capsule (10 mg of esomeprazole) at a time, once a day. The usual duration of administration is up to 4 weeks.
In general, for children aged 1 year or over, take 1 capsule (10 mg of esomeprazole) at a time, once a day. The usual duration of administration is up to 4 weeks.
For suppression of recurrence of gastric/duodenal ulcer associated with nonsteroidal anti-inflammatory drug or low-dose aspirin medication: In general, for adults, take 2 capsules (20 mg of esomeprazole) at a time, once a day.
To help the eradication of Helicobacter pylori: In general, for adults, take 2 capsules (20 mg of esomeprazole) concomitantly with 750 mg of amoxicillin hydrate (titer) and 200 to 400 mg of clarithromycin (titer) at a time, twice a day, for 7 days.
If this is insufficient, as an alternative, take 2 capsules (20 mg of esomeprazole) concomitantly with 750 mg of amoxicillin hydrate (titer) and 250 mg of metronidazole at a time, twice a day, for 7 days.
In any case, strictly follow the instructions.
- 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 taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

•Pay attention when taking any food containing St. John’s wort, since it may diminish medicinal effects.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, abnormal hepatic function, erosive gastritis, abdominal distension, gastric polyps, anemia, abdominal pain, photosensitivity reaction, rash, loose stool and taste abnormality. 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.

- respiratory distress, hives, facial/lips/tongue swelling [shock, anaphylaxis]
- general malaise, fever, nose/subcutaneous bleeding [pancytopenia, agranulocytosis, decreased platelets]
- nausea/vomiting, loss of appetite, yellowing of the skin and the white of eyes [fulminant hepatitis, liver dysfunction, jaundice, hepatic failure]
- fever, general malaise, rash/redness on the skin/eyes and in the mouth [toxic epidermal necrolysis, muco-cutaneo-ocular syndrome]
- fever, cough, shortness of breath [interstitial pneumonia]
- fever, rash, joint pain [interstitial nephritis]
- muscle pain of limbs, rigidity, numbness, red-brown urine [rhabdomyolysis]
- nausea/vomiting, convulsion, headache, consciousness disorder [hyponatraemia]
- confused consciousness and unable to have normal thoughts, impaired mind, hallucination [confusional state]

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 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.