Vonocab®

Vonoprazan

وونوکیب

(وونوپرازان)

VONOCAB TABLET 10mg
Each film coated tablet contains:
Vonoprazan ..... 10 mg.
as Fumarate (Mfg. Specs)
Product complies as per Innovator's Specifications.

VONOCAB TABLET 20mg
Each film coated tablet contains:
Vonoprazan ..... 20 mg.
as Fumarate (Mfg. Specs)
Product complies as per Innovator's Specifications.

INDICATIONS

• Treatment of gastric ulcer, duodenal ulcer, or reflux esophagitis; prevention of recurrent gastric or duodenal ulcer associated with low-dose aspirin administration; and prevention of recurrent gastric or duodenal ulcer associated with non-steroidal anti-inflammatory drug administration

• Adjunct therapy to Helicobacter pylori eradication in the following:
Gastric or duodenal ulcer, gastric mucosa-associated lymphatic tissue (MALT) lymphoma, idiopathic thrombocytopenic purpura, the stomach after endoscopic resection of early stage gastric cancer, or Helicobacter pylori gastritis

PROPOSED DOSAGE AND ADMINISTRATION

Treatment of gastric ulcer and duodenal ulcer:
The usual adult dosage is 20 mg of vonoprazan administered orally once daily. The usual treatment period should be up to 8 weeks for gastric ulcer and up to 6 weeks for duodenal ulcer.

• Treatment of reflux esophagitis:
The usual adult dosage is 20 mg of vonoprazan administered orally once daily. The usual treatment period is up to 4 weeks, but it may be extended up to 8 weeks if the efficacy is inadequate. For the maintenance therapy to prevent reocurrence or relapse of reflux esophagitis, the dose for oral use is 10 mg or 20 mg once daily.

• Prevention of recurrent gastric or duodenal ulcer associated with low-dose aspirin administration:
The usual adult dosage is 10 mg of vonoprazan administered orally once daily.

• Prevention of recurrent gastric or duodenal ulcer associated with non-steroidal anti-inflammatory drug administration:
The usual adult dosage is 10 mg of vonoprazan administered orally once daily.

• Adjunct therapy to Helicobacter pylori eradication:
For adults, the following 3-drug regimen should be administered orally at the same time twice daily for 7 days: 20 mg of vonoprazan, 750 mg (potency) of amoxicillin hydrate, and 200 mg (potency) of clarithromycin. The dose of clarithromycin may be increased up to 400 mg (potency)/dose twice daily, as clinically warranted.
In adults' patients in whom Helicobacter pylori eradication with a 3- drug regimen comprising vonoprazan or a proton pump inhibitor, amoxicillin hydrate, and clarithromycin was unsuccessful, the following 3 drugs should be administered orally twice daily for 7 6 days as an alternative treatment: 20 mg of vonoprazan, 750 mg (potency) of amoxicillin hydrate, and 250 mg of metronidazole.

SPECIAL PRECAUTIONS

Hepatotoxicity:
Hepatic function abnormalities including liver injury have been reported in clinical studies. Post marketing reports have also been received in patients treated with vonoprazan, many of which occurred shortly after initiation of treatment. Discontinuation of vonoprazan is recommended in patients who have evidence of liver function abnormalities or if they develop signs or symptoms suggestive of liver dysfunction.

Elevation of intragastric pH:
Administration of vonoprazan results in elevation of intragastric pH and is therefore not recommended to be taken with drugs for which absorption is dependent on acidic intragastric pH.
Symptomatic response to vonoprazan does not preclude the presence of gastric malignancy.

Renal Impairment:
Vonoprazan should be administered with care in patients with renal disorders as a delay in the excretion of vonoprazan may occur, which may result in an increase in the concentration of vonoprazan in the blood.

Hepatic Impairment:
Vonoprazan should be administered with care in patients with hepatic disorders as a delay in the metabolism and excretion of vonoprazan may occur, which may result in an increase in the concentration of vonoprazan in the blood.

Use in Children: Vonoprazan has not been studied in patients under 18 years of age.

Use in Elderly: Since the physiological functions such as hepatic or renal function are decreased in elderly patients in general, vonoprazan should be carefully administered.

Use In Pregnancy & Lactation:
No clinical studies have been conducted to date to evaluate vonoprazan in subjects who are pregnant or lactating. As a precaution, vonoprazan should not be administered to women who are or may be pregnant, unless the expected therapeutic benefit is thought to outweigh any possible risk. During treatment with vonoprazan, nursing should be avoided if the administration of this drug is necessary for the mother.

ADVERSE REACTIONS

The most commonly reported adverse reactions include constipation, diarrhea, enlarged feeling of abdomen, nausea, rash and edema. If any of these symptoms occur, consult with your doctor or pharmacist.

Overdosage
There is no experience of overdose with vonoprazan.
Vonoprazan is not removed from the circulatory by hemodialysis. If overdose occurs, treatment should be symptomatic and supportive.

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.

ہدایات:

- خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔ • بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
Kaizen Pharmaceuticals (Pvt.) Ltd.,
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