

# Bygerd™

Vonoprazan 10 mg & 20 mg Tablet



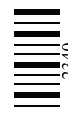
## Presentation

Bygerd™ 10 Tablet: Each film coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 10 mg.

Bygerd™ 20 Tablet: Each film coated tablet contains Vonoprazan Fumarate INN equivalent to Vonoprazan 20 mg.

## Description

Vonoprazan is a potassium competitive acid blocker (PCAB) and does not require activation by acid. It inhibits H<sup>+</sup>/K<sup>+</sup>-ATPase in a reversible and potassium-competitive manner. Vonoprazan resides on the acid production site of gastric parietal cells for a long time, thereby inhibiting gastric acid production. Vonoprazan exerts a strong inhibitory effect on formation of mucosal damage in upper part of the gastrointestinal tract.



## Indications

Bygerd (Vonoprazan) is indicated for:

1. Gastric ulcer, duodenal ulcer, reflux esophagitis, prevention of recurrence of gastric or duodenal ulcer during low-dose aspirin administration, prevention of recurrence of gastric or duodenal ulcer during non-steroidal anti-inflammatory drug (NSAID) administration.
2. Adjunct to *Helicobacter pylori* eradication in the following settings:

Gastric ulcer, 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.

## Dosage and Administration

### Gastric ulcer and duodenal ulcer

The usual adult dose for oral use is 20 mg of Vonoprazan once daily for 8-weeks to treat gastric ulcer and a 6-weeks to treat duodenal ulcer.

### Reflux esophagitis

The usual adult dose for oral use is 20 mg of Vonoprazan daily for a total of 4 weeks of treatment. If that dosing proves insufficient, the treatment should be continued up to 8 weeks.

For the maintenance therapy of reflux esophagitis showing recurrence and recrudescence, the dose for oral use is 10 mg of Bygerd (Vonoprazan) once daily. However, when the efficacy is inadequate, the dose may be increased up to 20 mg of Vonoprazan once daily.

### Prevention of recurrence of gastric or duodenal ulcer during low-dose aspirin administration

The usual adult dose for oral use is one tablet of 10 mg of Vonoprazan once daily.

### Prevention of recurrence of gastric or duodenal ulcer during non-steroidal anti-inflammatory drug (NSAID) administration

The usual adult dose for oral use is one tablet of 10 mg of Vonoprazan once daily.

### Adjunct to *Helicobacter pylori* eradication

For adults, the following three-drug regimen should be administered orally at the same time twice daily for seven days: 20 mg of Vonoprazan, 750 mg of amoxicillin hydrate and 200 mg of clarithromycin. The dose of clarithromycin may be increased as clinically warranted. However, dosage should not exceed 400 mg twice daily.

If *Helicobacter pylori* eradication with a three-drug regimen comprising a proton pump inhibitor, amoxicillin hydrate and clarithromycin has been unsuccessful, as an alternative treatment, adults should be administered the following three drugs orally twice daily for seven days: 20 mg of Vonoprazan, 750 mg of amoxicillin hydrate and 250 mg of metronidazole.

## 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 children less than 18 years of age

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

## Use in Pregnancy and Lactation

Vonoprazan should be used in pregnant women or women having possibilities of being pregnant only if the expected therapeutic benefit is thought to outweigh any possible risk.

It is advisable to avoid the administration of Vonoprazan to nursing mothers. However, when the administration is indispensable, nursing should be discontinued.

## Side-effects

### Following side-effects have been reported with the use of Vonoprazan:

Diarrhea, constipation, drug hypersensitivity (including anaphylactic shock), urticaria, hepatotoxicity, jaundice, rash, nausea, abdominal distension, edema and eosinophilia.

## Precaution

### For prevention of recurrent gastric or duodenal ulcer associated with low-dose aspirin administration:

Vonoprazan should be administered to patients who continue receiving low-dose aspirin to prevent thrombogenesis/embolization. A medical history of gastric or duodenal ulcer should be checked before starting administration of Vonoprazan.

### For prevention of recurrent gastric or duodenal ulcer associated with non-steroidal anti-inflammatory drug administration:

Vonoprazan should be administered to patients who continue receiving NSAID to control pain associated with rheumatoid arthritis, osteoarthritis, etc. A medical history of gastric or duodenal ulcer should be checked before starting administration of Vonoprazan.

### For adjunct therapy to *Helicobacter pylori* eradication

(1) The efficacy of *Helicobacter pylori* eradication in patients with advanced gastric MALT lymphoma has not been established.

(2) For patients with idiopathic thrombocytopenic purpura, the *Helicobacter pylori* eradication should be performed only in patients who are considered eligible for the eradication therapy in light of the guideline.

(3) The efficacy of the *Helicobacter pylori* eradication for treatment of the stomach after endoscopic resection of early stage gastric cancer has been established, but not for other therapies for prevention of gastric cancer development.

(4) Before Vonoprazan is administered to patients with *Helicobacter pylori* gastritis, the patients should be checked that they are *Helicobacter pylori* positive and endoscopically that they are affected by *Helicobacter pylori* gastritis.

## Contraindication

Vonoprazan is contraindicated in:

- Patients with hypersensitivity to Vonoprazan or to any excipient of the product.
- Patients receiving atazanavir sulphate, nelfinavir or rilpivirine hydrochloride.

## Drug Interactions

Vonoprazan should be administered with care when co-administered with the following drugs:

Drugs	Signs	Mechanism & Risk Factors
CYP3A4 inhibitors, Clarithromycin etc.	Blood conc. of Vonoprazan may increase.	It has been reported that blood conc. of Vonoprazan increased in concomitant use with clarithromycin.
Digoxin, Methyl digoxin	Effect of these drugs may be enhanced.	Gastric antisecretory effect of Vonoprazan may inhibit hydrolysis of digoxin, resulting in increase in the blood concentration of digoxin.
Itraconazole, Tyrosine kinase inhibitors Gefitinib, Nilotinib, Erlotinib	Effect of these drugs may be diminished	Gastric antisecretory effect of Vonoprazan may lead to a decrease in the blood concentration of these drugs.

## Overdosage

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

## Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

## Commercial pack

Bygerd™ 10 Tablet: Each box contains Vonoprazan 5 Alu-PVDC blister strips of 10 tablets.

Bygerd™ 20 Tablet: Each box contains Vonoprazan 5 Alu-PVDC blister strips of 10 tablets.