

# K-CAB<sup>®</sup> FILM-COATED TABLET

Tegoprazan (25 mg, 50 mg)

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## What K-CAB is used for

K-CAB is a potassium-competitive acid blocker (K-CAB) indicated for the treatment of erosive gastroesophageal reflux disease, treatment of non-erosive gastroesophageal reflux disease and gastric ulcer, prescribed for antibiotic combination therapy for *H. pylori* eradication in peptic ulcer and/or chronic atrophic gastritis. Additionally, it can be to maintenance of healed Erosive Gastroesophageal Reflux Disease <25 mg only>.

## How K-CAB works

Tegoprazan, which acts as a potassium-competitive acid blocker (K-CAB) that function to treat acid-related gastrointestinal disease by inhibiting reversibly the gastric (H<sup>+</sup>/K<sup>+</sup>-ATPase) that responsible for gastric acid secretion.

## Before you use K-CAB

### - When you must not use it

Do not take this medicine if:

- you are allergic to Tegoprazan or substituted benzimidazoles or any other ingredients of this medicine (listed in Product Description)
- Patients who take atazanavir, nelfinavir or rilpivirine-containing products.
- Breastfeeding women.
- Pregnant women.

### - Before you start to use it

Check with your doctor or pharmacist before taking K-CAB if you:

- Patients with hepatic or renal impairment.
- Elderly patients

## Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

## - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Inform your doctor or pharmacist if you are taking:

- Ketoconazole, itraconazole, ampicillin esters, atazanavir, iron salts, erlotinib, gefitinib, mycophenolate mofetil (MMF), nelfinavir, rilpivirine, clarithromycin, metronidazole, tetracycline and bismuth
- Digoxin or any drugs that may cause hypomagnesemia.
- Any acid-suppressing medications that is a similar therapeutic class with this drug over a long period of time (e.g., longer than one year).

Above-listed medicine might not exhaustive. Please consult with your doctor or pharmacist before taking any medicines with K-CAB.

## How to use K-CAB

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

### - How much to use

- Treatment of Erosive Gastroesophageal Reflux Disease:
  - 50 mg (2 tablets) once daily for 4 weeks.
  - For patients who do not recover or have persistent symptoms after 4 weeks, an additional 4-week treatment may be considered.
- Treatment of Non-Erosive Gastroesophageal Reflux Disease:

- 50 mg (2 tablets) once daily for 4 weeks.

### • Treatment of Gastric Ulcer:

- 50 mg (2 tablets) once daily for 8 weeks.

### • Eradication of *H. pylori* in peptic ulcer and/or chronic atrophic gastritis:

- 50 mg (2 tablets) twice daily for 7 days with amoxicillin 1 g and clarithromycin 500 mg.

### • Maintenance of healed Erosive Gastroesophageal Reflux Disease <25 mg only>.

- 25 mg (1 tablet) once daily for up to 24 weeks.

K-CAB can be taken with or without food.

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

Use this medicine for the duration that your doctor recommends.

### - If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

### - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

## While you are using K-CAB

### - Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using K-CAB.

Tell your doctor immediately if you become pregnant while using this medication.

Take K-CAB only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give K-CAB to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Be careful driving or operating machinery until you know how K-CAB affects you.

**Side effects**

Like all medicines, K-CAB can cause side effects, although not everybody gets them.

The AEs reported after taking K-CAB 25 mg Film-Coated Tablet in clinical trials Endoscopically-Confirmed Healed Erosive Gastroesophageal Reflux Disease are as follows:

Common AEs (which can occur in more than 1 out of 100 patient):

- Stomach irritation or discomfort (Gastritis erosive)
- Long-term inflammation of the stomach lining (chronic gastritis)
- Small growths in the stomach (gastric polyps)
- Diarrhoea
- Dizziness
- Runny or blocked nose, sore throat, or sneezing (nasopharyngitis)
- Cough

In addition to these symptoms, clinical trials have shown that adverse drug reactions that can occur in less than 1 out of 100 patients include:

- High levels of stomach acid hormone (hypergastrinaemia)
- Stomach pain
- indigestion (Dyspepsia)
- Small growths in the large intestine (Large intestinal polyps)
- Bladder infection (cystitis)
- Airway infection (bronchitis)
- Raised liver enzymes or bilirubin levels (seen in blood tests)

- Joint pain (arthralgia)
- Curved spine (scoliosis)
- Low bone strength (osteopenia)
- Hearing loss
- Lump in the neck area due to a thyroid swelling (thyroid mass)
- Fatty liver (hepatic steatosis).

The AEs reported after taking K-CAB 50 mg Film-Coated Tablet in clinical trials of Erosive Gastroesophageal Reflux Disease, Non-Erosive Gastroesophageal Reflux Disease and Gastric ulcer patients are as follows:

Common AEs (which can occur in more than 1 out of 100 patients)

- Nausea
- Diarrhoea
- Indigestion
- Nasopharyngitis
- Viral upper respiratory tract infection
- Chest discomfort

In addition to these symptoms, clinical trials have shown that adverse drug reactions that can occur in less than 1 out of 100 patients include upper abdominal pain, abdominal discomfort, constipation, abdominal pain, abdominal distension, gastric ulcer, anal haemorrhage, erosive duodenitis, flatulence, gastric polyps, gastroesophageal reflux disease, melena, folliculitis, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, blood creatine phosphokinase increased, blood urine present, red blood cells urine positive, blood gastrin increased, blood triglycerides increased, fatigue, myalgia, tendonitis, headache, seborrheic dermatitis, cough, nasopharyngitis, breast calcification, nocturia, gastrointestinal tract adenoma, ventricular extrasystoles, lymphadenitis, anaemia, insomnia, ear pain and thyroid cyst.

The AEs reported after taking this drug in clinical trials of *H. pylori* positive peptic ulcer and chronic atrophic gastritis patients are as follows:

Common AEs (which can occur in more than 1 out of 100 patient)

- Nausea
- Diarrhoea
- Indigestion
- Upper abdominal pain

- Abdominal pain
- Abdominal distension
- Blood creatine phosphokinase increased
- Inflammation of bladder
- Fatigue or weakness
- Headache
- Dizziness
- Unpleasant or altered taste sensation
- Urticaria
- Pruritus
- Erythema

In addition to these symptoms, clinical trials have shown that adverse drug reactions that can occur in less than 1 out of 100 patients include anal incontinence, blood lactate dehydrogenase increased, folliculitis, tonsillitis, migraine, rash, drug eruption, toxic skin eruption, palpitation, hot flush, flushing. Please contact your doctor or pharmacist for more information.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

**Storage and Disposal of K-CAB**

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

- What it looks like

**K-CAB 25 mg Film-Coated Tablet**

A light pink, oblong, film-coated tablet, engraved with "K|25" on one side and "|" on the other.

**K-CAB 50 mg Film-Coated Tablet**

A light pink, oblong, film-coated tablet, engraved with “K|50” on one side and “|” on the other

- Ingredients

- Active ingredient:

Tegoprazan

- Inactive ingredients:

D-Mannitol, Microcrystalline cellulose, Croscarmellose sodium, Hydroxypropyl cellulose, Colloidal silicon dioxide, Magnesium stearate, etc

- MAL number:

**K-CAB 25 mg Film-Coated Tablet**

MALXXXXXXXXXX

**K-CAB 50 mg Film-Coated Tablet**

MAL24096019AZ

**Manufacturer**

HK inno.N Corporation  
239, Osongsaengmyeong 2-ro,  
Osong-eup, Heungdeok-gu, Cheongju-si,  
Chungcheongbuk-do, Republic of Korea.

**Product Registration Holder**

Pharmaniaga Marketing Sdn. Bhd.  
(198401005734)  
No. 7, Lorong Keluli 1B,  
Kawasan Perindustrian Bukit Raja  
Selatan, Seksyen 7, 40000 Shah Alam,  
Selangor Darul Ehsan, Malaysia.

**Date of revision**

15/05/2026

**Serial Number**

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