

K-CAB TABLET 50MG

Tegoprazan (50mg)

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What K-CAB Tablet 50mg is used for

K-CAB Tablet 50mg 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. Additionally, it can be prescribed for antibiotic combination therapy for *H.pylori* eradication in peptic ulcer and/or chronic atrophic gastritis.

How K-CAB Tablet 50mg 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⁺/K⁺-ATPase) that responsible for gastric acid secretion.

Before you use K-CAB Tablet 50mg

-When you must not use it:

- Patients with hypersensitivity and/or a medical history of hypersensitivity to this drug, any of the product components or substituted benzimidazoles.
- Patients who take atazanavir, nelfinavir or rilpivirine-containing products.
- Breastfeeding women.
- Pregnant women.

-Before you start to use it

Before taking K-CAB Tablet 50mg, please tell your doctor or pharmacist if you have any of the following:

- Hypersensitivity and/or a medical history of hypersensitivity to this drug, any of the product components or substituted benzimidazoles.

- Patients with hepatic or renal impairment.
- Elderly patients.
- If you are planning to be pregnant or are pregnant.
- If breastfeeding is scheduled or in the process of breastfeeding.

-Taking other medicines

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

Some of medicines might have interaction when taken together with K-CAB Tablet 50 mg which includes:

- 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 1 year).

Above-listed medicine might not exhaustive. Please consult with your doctor or pharmacist before taking any medicines with K-CAB Tablet 50mg.

How to use K-CAB Tablet 50mg

-How much to use

- Treatment of Erosive Gastroesophageal Reflux Disease:
 - 50mg 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:
 - 50mg once daily for 4 weeks.
- Treatment of Gastric Ulcer:
 - 50mg once daily for 8 weeks.
- Eradication of *H.pylori* in peptic ulcer and/or chronic atrophic gastritis:
 - 50mg twice daily for 7 days with amoxicillin 1g and clarithromycin 500mg.

K-CAB Tablet 50mg can be taken with or without food.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

You should continue to use these tablets for as long as your doctor tells you to. Do not stop taking the tablets or alter the dosage without consulting your doctor.

-If you forget to use it

If you miss or vomit a dose of K-CAB Tablet 50mg, do not make up the dose. Take your next dose at your regular scheduled time.

-If you use too much (overdose)

If you take too much K-CAB Tablet 50mg, contact your doctor or hospital for advice immediately.

While you are using K-CAB Tablet 50mg

-Things you must do

- Always take K-CAB Tablet 50mg exactly according to the instructions given by your doctor or pharmacists. Check with your doctor or pharmacist if you are unsure.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
- Inform your doctor or pharmacist immediately if you notice any side effects, or if the side effects get serious or anything else that make you feel unwell.
- If you become pregnant, or plan on becoming pregnant while taking K-CAB Tablet 50mg inform your doctor immediately.

Things you must not do

- Do not stop taking K-CAB Tablet 50mg without consulting your doctor.
- Do not use K-CAB Tablet 50mg after the expiry date which is stated on the carton and bottle.
- Do not give K-CAB Tablet 50mg to anyone else, even if they have the same condition as you.

K-CAB TABLET 50MG

Tegoprazan (50mg)

Things to be careful of

K-CAB Tablet 50mg is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary.

Side effects

Like other drugs, K-CAB Tablet 50mg may cause AEs, but not all patients will be affected. The AEs reported after taking this drug 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 abdominal pain upper, 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
- Abdominal pain upper
- 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.

If you are concerned about any side effects that you may be experiencing, or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and K-CAB Tablet 50mg

-Storage

Keep K-CAB Tablet 50mg out of sight and reach of children.

Store at 1~30°C in the original package.

Do not use this medicine after the expiry date stamped on the pack.

-Disposal

If it is expired or is no longer needed, dispose of it safely.

Product Description

What it looks like

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

MALxxxxx

Product Registration Holder & Manufacturer

Product Registration Holder Pharmaniaga Marketing Sdn. Bhd. (198401005734)

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