

PREVACID FDT TABLETS

Lansoprazole (15mg, 30mg)

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What Prevacid is used for

Prevacid is used in children 12 to 17 years old:

- Short-term treatment of symptomatic gastro-esophageal reflux disease (GERD) and erosive esophagitis (disease with symptoms caused by return flow of gastric acid)

In adults:

- Treatment of gastric, intestinal, gastrointestinal ulcers and reflux esophagitis (inflammation of the esophagus caused by the return flow of fluid from stomach)
- Relief of heartburn and / or upper epigastric pain associated with acid-related indigestion
- Treatment and prevention of Non-Steroidal Anti-inflammatory Drugs (NSAIDs) - associated gastric and intestinal ulcer and relief of symptoms
- Hormone producing tumor in the pancreas causing excess acid in the stomach (Zollinger-Ellison-Syndrome) and other pathological hypersecretory conditions
- Eradication of *H. pylori* in people with gastric and intestinal ulcer in combination with two appropriate antibiotics

How Prevacid works

Prevacid belongs to a group known as Proton Pump Inhibitors (PPIs). Prevacid reduces the amount of acid in your stomach.

Prevacid may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

Before you use Prevacid

- When you must not use it

You should not take Prevacid if you are allergic to lansoprazole or any of the other ingredients of this medicine.

- Before you start to use it

Before you take Prevacid, tell your doctor if you:

- have liver problems
- have kidney problems
- Are pregnant or plan to become pregnant. It should be used by pregnant women with caution only if needed.
- are breast-feeding or planning to breast-feed. You and your doctor should decide if you will take Prevacid or breast-feed. You should not do both without first talking with your doctor.
- Are due to have specific blood test (Chromogranin A).
- Prevacid can cause rare but severe skin reactions that may affect any part of your body. These serious skin reactions may need to be treated in a hospital and may be life threatening; Skin rash which may have blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet). You may also have fever, chills, body aches,

shortness of breath, or enlarged lymph nodes. Stop taking Prevacid and call your doctor right away. These symptoms may be the first sign of a severe skin reaction.

Doctor will prepare some test to diagnose cancers when gastric ulcer is suspected, as symptoms may be alleviated and diagnosis delayed.

- Taking other medicines

Tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Prevacid may affect how other medicines work, and other medicines may affect how Prevacid works. Especially tell your doctor if you take:

- Atazanavir or nelfinavir (medicines for Human Immunodeficiency Virus (HIV))
- Methotrexate (chemotherapy medication used to treat cancer)
- Theophylline (treatment for respiratory diseases)
- Warfarin (prevent blood clotting)
- Sucralfate. Prevacid should be taken at least 30 minutes prior to sucralfate. (used to treat certain intestinal ulcers)
- Ketoconazole (antifungal medication)
- Ampicillin esters (antibiotic)
- Iron salts (to treat iron-deficiency)
- Digoxin (to treat various heart conditions)

How to use Prevacid

- How much to use

- General dose - 30mg once daily
- Treatment for Zollinger-Ellison dose is adjusted

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according to symptom. • Treatment and prevention of NSAID-associated gastric and intestinal ulcers and relief of symptoms – 15mg or 30mg once daily • H.pylori infection – 30mg twice daily with combination of antibiotics: ○ 2x1000mg amoxicillin + 2x250-500mg clarithromycin/ day ○ 2x500mg metronidazole + 2x250-500mg clarithromycin/day	- <u><i>If you use too much (overdose)</i></u> If you take too much Prevacid, call your doctor or go to the nearest hospital emergency room right away. While you are using it - <u><i>Things you must do</i></u> Place tablet on the tongue and allow it to dissolve with or without water, until the particles can be swallowed. Alternatively, for children or other individuals who have difficulty swallowing tablets, Prevacid can be delivered in two different ways.	- <u><i>Things you must not do</i></u> Prevacid should not be chewed. - <u><i>Things to be careful of</i></u> • There is increased risk for bone fractures of the hip, wrist or spine for individuals who received high-doses, or used more than a year or longer. • There is an increased risk of bacteria infection (e.g. Clostridium difficile). • Liver enzymes should be monitored for long-term use.
- <u><i>When to use it</i></u> Take Prevacid as advised by your doctor. - <u><i>How long to use it</i></u> • Intestinal ulcer – 4 weeks • Gastric and gastrointestinal ulcer – 8 weeks • Reflux esophagitis -4 to 8 weeks • H.pylori infection - 7 days • Treatment for Zollinger-Ellis is not limited. • Short-term treatment for children – 8 weeks • Treatment and prevention of NSAID-associated gastric and intestinal ulcers – 4 to 8 weeks • Acid-related indigestion – 2 to 4 weeks - <u><i>If you forget to use it</i></u> If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose, and take the next dose at your regular time. Do not take 2 doses of Prevacid at the same time.	Prevacid FDT Oral Syringe: Prevacid can be taken as follows: Place a 15 mg tablet in oral syringe and draw up approximately 4 ml of water, or place a 30 mg tablet in oral syringe and draw up approximately 10 ml of water. Shake gently to allow for a quick dispersal. After the tablet has dispersed, take the contents within 15 minutes. Refill the syringe with approximately 2 ml (5 ml for the 30 mg tablet) of water, shake gently, and take any remaining contents. Prevacid FDT-Nasogastric Tube Use (> 8 French) Prevacid can be taken as follows: Place 15 mg tablet in a syringe and draw up 4 ml of water, or place a 30 mg tablet in a syringe and draw up 10 ml of water. Shake gently to allow for a quick dispersal. After the tablet has dispersed, inject through the nasogastric tube into the stomach within 15 minutes. Refill the syringe with approximately 5 ml of water, shake gently, and flush the nasogastric tube.	Side Effects These side effects of Prevacid may occur: • Subacute Cutaneous Lupus Erythematosus (SCLE) (Frequency “not known”) • Kidney problems (interstitial nephritis) • Hypomagnesaemia (Frequency “not known”: Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood) • Fracture (Frequency “uncommon”: Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).) • Clostridium Difficile Diarrhea (Severe diarrhoea which may be caused by an infection (Clostridium difficile) in your intestines.) • Fundic Gland Polyps (Benign) (Frequency “Common”: Benign polyps in the stomach) • Vitamin B12 Deficiency (Proton pump inhibitors may cause vitamin B12

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- deficiency.)
- Inflammation in the large bowel. (Frequency ‘not known’: Inflammation in the large bowel, that causes persistent watery diarrhea)
- Elevated liver enzymes
- Rash
- Low red blood cells
- Decrease in white blood cells
- Diarrhoea
- Constipation
- Dry mouth
- Headache
- Sleepiness
- Benign polyps in the stomach

When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- Subacute Cutaneous Lupus Erythematosus (SCLE).**
Rash (especially in areas exposed to the sun), possibly with pain in the joints. SCLE frequency “not known”.
- Drug reaction with eosinophilia and systemic symptoms (DRESS).**
Drug-induced hypersensitivity reaction
- Kidney problems (Tubulointerstitial Nephritis)**
Fever that do not go away, extreme tiredness, pus/ blood in urine
- Hypomagnesaemia.**
Involuntary muscle contractions, disorientation, convulsions, dizziness,

increased heart rate.
Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes
Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood (hypomagnesaemia).
Frequency “not known”.

- Bone fracture.** People who are taking multiple daily doses of proton pump inhibitor medicines for a long period of time may have an increased risk of fractures of the hip, wrist or spine. Tell your doctor if you have fracture in the hip, wrist or spine, or osteoporosis, or if you are taking corticosteroids (which can increase the risk of osteoporosis). Frequency “uncommon”.
- Vitamin B-12 Absorption.**
Malabsorption of vitamin B-12 may happen if you are taking acid-suppressing medications for a long period of time (e.g longer than 3 years).
- Clostridium Difficile* Diarrhea**
Watery stool, stomach pain and fever that do not go away. Severe diarrhea which may caused by an infection (*Clostridium difficile*) in your intestines.
- Microscopic Colitis**
Inflammation in the large bowel, that causes

persistent watery diarrhea
Frequency “not known”

- Hyponatremia**
Reduction of sodium levels in the blood
- Severe skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP), erythema multiforme, and subacute cutaneous lupus erythematosus). You may also have joint pain or flu-like symptoms, a fever, swollen glands (e.g. in the armpit) and blood tests may show changes in certain white blood cells or liver enzymes

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.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Prevacid

- Storage

Store Prevacid below 30°C. Keep Prevacid and all medicines out of the reach of children.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

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Prevacid is supplied as white to yellowish white uncoated tablet with orange to dark brown speckles.

- Ingredients

- Active ingredient

Lansoprazole

- Inactive ingredients

Red ferric oxide, strawberry duramome 860017 TD0590, magnesium carbonate, methacrylic acid copolymer LD (Eudragit L30D-55), ethyl acrylate methyl methacrylate copolymer dispersion, crospovidone, triethyl citrate, polysorbate 80, macrogol 6000, d-mannitol, anhydrous citric acid, magnesium stearate, talc, aspartame, microcrystalline cellulose, lactose microcrystalline cellulose spheres, low substituted hydroxypropylcellulose, hydroxypropylmethylcellulose 2910, glyceryl monostearate, yellow ferric oxide, titanium oxide.

- MAL Number

15mg: MAL08042459ARZ

30mg: MAL08042460ARZ

Manufacturer

Kokando Co, Ltd, 9-1,
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Toyama 930-0055, Japan

Product Registration Holder

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