

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, tells 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.

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 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

- When to use it

Take Prevacid as advised by your doctor.

- How long to use it

- Intestinal ulcer – 4

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- weeks
- Gastric and gastrointestinal ulcer – 8 weeks
- Reflux esophagitis -4 to 8 weeks
- H.pylori infection - 7 days
- Treatment for Zollinger-Ellisson 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

- If you forget to use it

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.

- If you use too much (overdose)

If you take too much Prevacid, call your doctor or go to the nearest hospital emergency room right away.

While you are using it

- Things you must do

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.

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.

- Things you must not do

Prevacid should not be chewed.

- Things to be careful of

- 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.

Side Effects

These side effects of Prevacid may infrequently occur:

- Elevated liver enzymes
- Rash

- Low red blood cells
- Decrease in white blood cells
- Diarrhoea
- Constipation
- Dry mouth
- Headache
- Sleepiness

Hypomagnesemia (Low magnesium level): has been rarely been reported in people treated with PPIs for at least three months (in most cases after a year of therapy). Serious adverse events include involuntary muscle contractions (tetany), irregular heart beat and seizures.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems/ Side Effects/ AEFI/ Vaccine Safety)

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

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

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- ***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

Takeda Pharmaceutical Company Limited, Osaka Plant, 17-85, Jusohonmachi 2-Chome, Yodagawa-Ku, 532-8686 Osaka, Japan

Product Registration Holder

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