PREVACID® 15, 30mg FDT
Abbreviated Prescribing Information

Please refer to full package insert before prescribing (25 March 2021 CCDS v27.0)

Composition: Lansoprazole 15mg, 30mg **Indications:** Gastric ulcer, duodenal ulcer, stomal ulcer and reflux esophagitis, relief of reflux-like symptoms (e.g. heartburn) and / or ulcer-like symptoms (e.g. upper epigastric pain) associated with acid-related dyspepsia, treatment and prophylaxis of NSAID-associated benign gastric ulcer, duodenal ulcers and relief of symptoms in patients requiring continued NSAID treatment, eradication of H. pylori from the upper gastrointestinal tract in patients with peptic ulcer (duodenal or benign gastric ulcer) when used in combination with appropriate antibiotics, Zollinger-Ellison syndrome (and other Pathological hypersecretory conditions), short-term treatment of symptomatic GERD and erosive esophagitis for children (12-17 years of age) **Dosage:** Adult Duodenal ulcer 30 mg once daily for 4 weeks, Gastric & stomal ulcer 30 mg once daily for 8 weeks, Reflux esophagitis 30 mg once daily for 4-8 weeks, Zollinger-Ellison-Syndrome Adjust dose according to the patient's signs & symptoms, Eradication of H pylori To be taken twice daily for 1 week: Prevacid FDT 30 mg + amoxicillin 1 g or metronidazole 400 mg + clarithromycin 250-500 mg, Acid-related dyspepsia 30 mg once daily for 2-4 weeks, Short term treatment of symptomatic GERD and Erosive Esophagitis (12-17 years): 30mg once daily for up to 8 weeks, Treatment & prophylaxis of NSAID-associated benign gastric ulcers, duodenal ulcers & relief of symptoms in patients requiring continued NSAID treatment 15 or 30 mg once daily for 4-8 weeks for treatment. Prophylaxis: 15 or 30mg once daily. **Administration:** Place tab on the tongue & allow it to disintegrate, with or without water; do not chew; tab may also be administered via an oral syringe or a nasogastric tube ≥8 French; for oral syringe, place a 15mg tablet in oral syringe and draw up approximately 4mL of water, or place a 30mg tablet in oral syringe and draw up approximately 10mL of water, shake syringe to disperse the tab & administer within 15 min, refill syringe with 2 mL of water (5mL for the 30mg tablet), shake gently & administer any remaining contents. For nasogastric tube, place 15mg tablet in a syringe and draw up 4mL of water, or place a 30mg tablet in a syringe and draw up 10mL of water, shake gently to allow for a quick dispersal, inject through the nasogastric tube into the stomach within 15 minutes, refill the syringe with approximately 5mL of water, shake gently, and flush the nasogastric tube. **Warnings and Precautions:** Careful administration, regular surveillance, Subacute Cutaneous Lupus Erythematosus (SCLE), Bone fracture, Clostridium difficile associated diarrhea, Hypomagnesemia, Influence on Vitamin B12 Absorption, Interference with laboratory tests, HIV Protease Inhibitors **Adverse Drug Reaction:** Hypersensitivity, hepatic enzyme & hematological changes, anemia, leucopenia, eosinophilia or thrombocytopenia, GI disorders, headache, sleepiness, depressed state, insomnia, dizziness, tremor, hyponatremia, hypomagnesaemia, vitamin B12 deficiency, hypocalcemia, hypokalemia, tubulointerstitial nephritis (TIN) with possible progression to renal failure, fracture of the hip, wrist or spine, Subacute cutaneous lupus erythematosus (SCLE), Clostridium difficile associated diarrhea, Interstitial pneumonia **Drug Interactions:** Lansoprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (e.g., ketoconazole, ampicillin esters, iron salts, digoxin). Co-administration of lansoprazole is not recommended with HIV protease inhibitors for which absorption is dependent on acidic intragastric pH such as atazanavir, nelfinavir. Concomitant use with high-dose Methotrexate may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities. There have been reports of increased INR and prothrombin time in patients receiving PPIs and warfarin concomitantly. Concomitant administration of lansoprazole and tacrolimus may increase whole blood levels of tacrolimus. Inhibitors of CYP2C19 such as fluvoxamine would likely increase the systemic exposure of to lansoprazole. **Storage condition:** Store below 30°C. **Name and Address of Marketing Authorisation (MA) Holder:** Takeda Malaysia Sdn Bhd, Unit TB-L13-1, Level 13, Tower B, Plaza 33, No.1 Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor, Malaysia.

Further information is available on request.

Suspected Adverse events should be reported to Takeda at: AE.VMAPS@takeda.com

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