CONTROLOC® 20mg, 40 mg Gastro-resistant tablets
Abbreviated Prescribing Information

Please refer to full package insert before prescribing (October 2022 CCDSv9/9.1)

Composition: Pantoprazole sodium 20mg, 40mg **Indication: 20mg:** For the treatment of mild gastroesophageal reflux disease and associated symptoms (e.g. heartburn, acid regurgitation, pain on swallowing). For long-term management and prevention of relapse in reflux oesophagitis. Prevention of gastroduodenal ulcers induced by nonselective non-steroidal anti-inflammatory drugs (NSAIDs) in patients at risk with a need for continuous NSAID treatment **40mg:** In combination with two appropriate antibiotics for the eradication of Helicobacter pylori in patients with peptic ulcers with the objective of reducing the recurrence of duodenal and gastric ulcers caused by this microorganism, Duodenal ulcer, Gastric ulcer, Moderate and severe cases of inflammation of the esophagus (reflux esophagitis), Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions **Dosage: 20mg:** Adults and adolescents 12 years of age and above: Mild reflux disease and associated symptoms (e.g. heartburn, acid regurgitation, pain on swallowing): 20mg per day. Long-term management and prevention of relapse in reflux oesophagitis: 20mg per day, increasing to 40 mg pantoprazole per day if a relapse occurs, after healing of the relapse the dosage can be reduced again to 20 mg pantoprazole. Adults: Prevention of gastroduodenal ulcers induced by non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in patients at risk with a need for continuous NSAID treatment: 20mg per day. **40mg:** Adults and adolescents 12 years of age and above: Treatment of moderate and severe reflux oesophagitis: 40mg per day. Adults: Eradication of H. pylori in combination with two appropriate antibiotics: Refer to package insert. Treatment of gastric and duodenal ulcer: 40mg per day. Increase to 2 tablets 40mg daily when there has been no response to other treatment. Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions: 80mg daily. Not recommended for use in children below 12 years of age. **Administration:** swallowed whole, do not chew or crush **Contraindications: 20mg & 40mg:** Known hypersensitivity to the active ingredient or/and any of the other constituents **40mg:** Must not be used in combination treatment for eradication of Helicobacter pylori in patients with moderate to severe liver or kidney function disturbances since currently no clinical data are available on the efficacy and safety of Controloc 40 mg in combination treatment of these patients **Warnings and Precautions:** Bone fracture, Clostridium difficile associated diarrhea, hypomagnesemia, influence on vitamin B12 absorption, interference with laboratory tests, hepatic impairment, HIV protease inhibitors, Methotrexate, gastric malignancy, regular surveillance, Subacute Cutaneous Lupus Erythematosus (SCLE), Severe Cutaneous Adverse Reactions **Adverse Drug Reaction:** Fundic gland polyps (benign) **Pregnancy & Lactation:** Pantoprazole should not be used during pregnancy unless clearly necessary. A decision on whether to continue/discontinue breastfeeding or to continue/discontinue therapy with pantoprazole should be made taking into account the benefit of breastfeeding to the child and the benefit of pantoprazole therapy to women **Drug Interactions:** Pantoprazole may interfere with the absorption of drugs where gastric pH is an important determinant of oral bioavailability. Co-administration of pantoprazole 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. No dose adjustment of clopidogrel is necessary when administered with an approved dose of pantoprazole. Concomitant administration of pantoprazole and tacrolimus may increase whole blood levels of tacrolimus. Inhibitors of CYP2C19, such as fluvoxamine, would likely increase the systemic exposure of pantoprazole. There have been reports of increased INR and prothrombin time in patients receiving PPIs and warfarin or phenoprocoumon concomitantly **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.

Prescribing information is available on request.

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