DEXILANT 30mg, 60mg delayed-release Capsules

Abbreviated Product Information

Please refer to full package insert before prescribing (October 2022 CCDS v 11.0)

Composition: Dexlansoprazole 30 mg and 60 mg **Indication:** Healing of all grades of erosive esophagitis (EE) for up to 8 weeks in patients 12 years of age and older, maintaining healing of EE and relief of heartburn for up to 4 months in adolescents 12 to 17 years of age and up to 6 months in adults, treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD) for 4 weeks in patients 12 years of age and older **Dosage: Healing of EE** 60 mg once daily for up to 8 weeks **Maintenance of healed EE and heartburn relief** 30 mg once daily (controlled studies did not extend beyond 6 months in adults, and beyond 4 months in adolescents 12 to 17 years of age) **Symptomatic non-erosive GERD (NERD)** 30 mg once daily for 4 weeks **Administration:** Can be taken without regard to food. Swallowed whole, should not be chewed. For patients who have difficulty swallowing capsules, administration with water in an oral syringe or via a nasogastric (NG) tube (≥16 French) **Contraindications:** Contraindicated in patients with known hypersensitivity to any component of the formulation. Hypersensitivity and anaphylaxis have been reported with DEXILANT use. **Warnings and Precautions:** Gastric malignancy, *Clostridium difficile* associated diarrhoea, bone fracture, hypomagnesemia, influence on vitamin B-12 absorption and interference with laboratory tests, Subacute Cutaneous Lupus Erythematosus (SCLE), regular surveillance and concomitant use with Methotrexate, Subacute Cutaneous Lupus Erythematosus (SCLE) **Adverse Drug Reaction:** Diarrhoea, abdominal pain, nausea, upper respiratory tract infection, vomiting and flatulence **Pregnancy & Lactation:** DEXILANT should be used during pregnancy only if clearly needed. It is not known whether dexlansoprazole is excreted in human milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother **Drug Interactions:** Drugs with pH-dependent absorption pharmacokinetics, tacrolimus and methotrexate. There have been reports of increased INR and prothrombin time in patients receiving PPIs and warfarin concomitantly. No dose adjustment of clopidogrel is necessary when administered with an approved dose of DEXILANT. Concomitant administration of dexlansoprazole and tacrolimus may increase whole blood levels of tacrolimus. Concomitant administration of PPIs and methotrexate (primarily at high dose) may elevate and prolong serum levels of methotrexate and/or its metabolite. **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