TEGCISE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for TEGCISE [Tegoprazan Tablets 50 mg.]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES

MECHANISM OF ACTION: Tegoprazan is a potassium-competitive acid blocker (P-CAB) that reversibly blocks gastric acid secretion by competitively binding with potassium to the proton pumps (H+/ K+-ATPase) present in gastric wall cells.

INDICATIONS: TEGCISE is indicated for the treatment of erosive gastroesophageal reflux disease, treatment of non-erosive gastroesophageal reflux disease and treatment of gastric ulcer

DOSAGE AND ADMINISTRATION: *Treatment of erosive gastroesophageal reflux disease* - 50 mg once daily for 4 weeks. For patients who do not heal or have persistent symptoms after 4 weeks, an additional 4-week treatment may be considered. *Treatment of non-erosive gastroesophageal reflux disease* - 50 mg once daily for 4 weeks. *Treatment of gastric ulcer* - 50 mg once daily for 8 weeks.

CONTRAINDICATION: Patients with Hypersensitivity to tegoprazan, any of the product components or substituted benzimidazoles. Patients who take atazanavir, nelfinavir or rilpivirine-containing products. Pregnant women or nursing mothers.

WARNINGS & PRECAUTIONS: Safety and efficacy of tegoprazan have not been established in patients with hepatic impairment, renal impairment, pediatric and adolescent. In general, tegoprazan should be administered to the elderly patients with caution, keeping in mind the greater frequency of decreased physiological functions, such as liver or kidney.: Daily treatment with any acid-suppressing medications over a long period of time (e.g., longer than 3 years) may lead to malabsorption of cyanocobalamin (Vitamin B_{12}) caused by hypo- or achlorhydria. Gastric polyp was observed with long term use of P-CABs and tegoprazan. Gastric ulcer: Do not administer for patient who do not require maintenance therapy. For patients expected to be on prolonged treatment or who take tegoprazan with medications such as digoxin or drugs that may cause hypomagnesemia (e.g., diuretics), healthcare professionals may consider monitoring magnesium levels prior to initiation of treatment and periodically. Serious adverse reactions include tetany, arrhythmias, and seizures.

DRUG INTERACTIONS: Tegoprazan is metabolized in liver by CYP3A4. In vitro studies have shown that ketoconazole, a CYP3A4 inhibitor, significantly inhibited the metabolism of tegoprazan, and while inhibitors of CYP1A2, CYP2C9, CYP2C19, CYP2D6 did not significantly reduced the metabolism of tegoprazan. Concomitant use of tegoprazan with CYP3A4 inhibitors may elevate exposure of tegoprazan. Absorption of drugs such as digoxin can increase during treatment with tegoprazan. Concomitant use of atazanavir, nelfinavir and rilpivirine with tegoprazan is contraindicated. Due to its effects on gastric acid secretion, tegoprazan can reduce the absorption of drugs where gastric pH is an important determinant of their bioavailability. Like with other drugs that decrease the intragastric acidity, the absorption of drugs such as ketoconazole, itraconazole, ampicillin ester, atazanavir, iron salts, erlotinib, gefitinib and mycophenolate mofetil (MMF) can decrease during treatment with tegoprazan.

ADVERSE REACTIONS: Nausea, diarrhoea, dyspepsia, nasopharyngitis, viral upper respiratory tract infection, chest discomfort, abdominal pain upper, abdominal distension, dysgeusia, headache, urticaria, constipation, abdominal discomfort, dry mouth, eructation, flatulence, noncardiac chest pain, dizziness etc.

MARKETED BY:

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(Additional information is available on request)