

# Tesod<sup>®</sup>

Tegaserod

## **Composition:**

Tesod<sup>®</sup> Tablet: Each tablet contains Tegaserod INN 6 mg (as Tegaserod Hydrogen Maleate INN).

## **Pharmacology:**

Tesod<sup>®</sup> (Tegaserod) is a serotonin type-4 (5HT<sub>4</sub>) receptor partial agonist.

Tesod<sup>®</sup> binds with high affinity at human 5HT<sub>4</sub> receptors, present on caudate membranes, whereas it has no appreciable affinity for human recombinant 5HT<sub>3</sub> receptors or human recombinant dopamine D<sub>2</sub> receptors. In vitro and animal study has revealed that tegaserod can trigger the peristaltic reflex via 5HT<sub>4</sub> receptor activation and thereby enhance basal motor activity and normalize impaired GI motility.

## **Indication and Usage:**

Tesod<sup>®</sup> (Tegaserod) is indicated for the symptomatic treatment of irritable bowel syndrome with constipation (IBS-C) in patients whose main symptoms are constipation and abdominal pain/or discomfort. The maximum duration of treatment is 12 weeks and treatment should be discontinued if there has been no response after 4 weeks.

## **Dosage and Administration:**

General recommended dosage: Tesod<sup>®</sup>, 6 mg b.i.d. taken orally with a glass of water 30 minutes before meal. The maximum duration of treatment is 12 weeks and treatment should be discontinued after 4 weeks if no response has occurred.

Renal impairment: No dosage adjustment is required in patients with mild to moderate renal impairment. Tegaserod is not recommended in patients with severe renal impairment.

Hepatic impairment: No dosage adjustment is required in patients with mild to moderate hepatic impairment, however, caution is recommended when using Tegaserod in this patient population. Tegaserod has not been studied in patients with severe hepatic impairment, and therefore, it is not recommended in this group.

Elderly: No dosage adjustment is required in the elderly.

**Precaution:**

General: Diarrhea was reported in some of the patients receiving Tegaserod in the Phase III clinical studies. Caution is required in patients in whom increased diarrhea could have negative effects. Patients who are currently experiencing or frequently experience diarrhea should not initiate therapy with Tegaserod.

Pregnancy: In view of limited experience in human, use of Tegaserod during pregnancy is not recommended.

Nursing mothers: Tegaserod should not be prescribed to nursing mothers.

Use in children: The safety and effectiveness of Tegaserod in children have not been established and use in this group is not recommended.

Geriatric use: Dose adjustment is not necessary when administering Tegaserod to patients over 65 years old.

**Information for Patient:**

Patient should be advised to take Tegaserod (6 mg twice daily) 30 minutes before meal.

Patient should also be made aware of the possible occurrence of diarrhea during therapy. In most cases, the diarrhea occurred early, is transient, is most often observed as a single episode during the 12-week treatment period, and resolved with continued therapy.

Patients should be instructed to consult their physician if they experience new or worsening abdominal pain not typical of their IBS symptoms.

**Drug Interaction:**

No clinically relevant drug-drug interactions have been observed with dextromethorphan, theophylline, digoxin, oral contraceptives, and warfarin.

**Side Effect:**

Abdominal pain, diarrhea, nausea, flatulence, headache, fatigue, back pain, etc.

**Storage Condition:**

Store at a cool and dry place, protected from light and moisture.

**How Supplied:**

Tesod<sup>®</sup> Tablet: Box containing 3 x 10 tablets in Alu-Alu blister pack.

*Manufactured by :*



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