In Vitro Studies Where the Drug Interaction Potential Was Not Further Evaluated Clinically

**Drug interactions with CYP enzymes**

**Warfarin:**
Administration of a single dose of digoxin following ZELNORM 6 mg twice daily for 4 days reduced the mean Cmax and AUC of digoxin by approximately 15%. This was not considered to be clinically important.

Administration of omeprazole 20 mg once daily for four days followed by ZELNORM 6 mg twice daily on day four increased the mean tegaserod AUC and Cmax by 29% and 76%, respectively. This was also not considered to be clinically important.

**Omeprazole:**
Administration of omeprazole 20 mg once daily for four days followed by ZELNORM 6 mg twice daily on day four increased the mean tegaserod AUC and Cmax by 29% and 76%, respectively. This was also not considered to be clinically important.

**Digoxin:**
Administration of a single dose of digoxin following ZELNORM 6 mg twice daily for 4 days reduced the mean Cmax and AUC of digoxin by approximately 15%. This was not considered to be clinically important.

**Importance of Monitoring Drug Interactions**

It is important to monitor drug interactions carefully, as they can significantly affect the efficacy and safety of tegaserod.

**Tegaserod and Other Drugs**

Tegaserod may interact with other drugs, and it is important to consult with a healthcare provider before starting any new medication.

**NURSING MOTHERS**

Reproduction studies have been conducted in rats and rabbits, and there was no evidence of fetal toxicity. However, tegaserod should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

**Pediatric Use**

The safety and effectiveness of tegaserod in children have not been established. It is not recommended for use in children.

**Drug Interactions with QT Interval**

Tegaserod has the potential to prolong the QT interval in vitro, and it is important to monitor patients for any signs of electrolyte disturbances or QT interval prolongation.

**Special Populations**

**Geriatric Patients**

Older adults may be more sensitive to the effects of tegaserod, and it is important to monitor them carefully for any signs of adverse effects.

**Diabetes Mellitus**

Tegaserod may affect blood glucose levels, and it is important to monitor patients with diabetes for any changes in glycemic control.

**Hypothyroidism**

Tegaserod may affect thyroid function, and it is important to monitor patients with hypothyroidism for any changes in thyroid function.

**Hypertension**

Tegaserod may affect blood pressure, and it is important to monitor patients with hypertension for any changes in blood pressure.

**Hyperkalemia**

Tegaserod may affect potassium levels, and it is important to monitor patients for any signs of hyperkalemia.

**Hypokalemia**

Tegaserod may affect potassium levels, and it is important to monitor patients for any signs of hypokalemia.

**Drug-induced liver injury**

Tegaserod has been associated with drug-induced liver injury, and it is important to monitor patients for any signs of liver dysfunction.

**Malignancy**

Tegaserod has been associated with malignancy, and it is important to monitor patients for any signs of malignancy.

**Seizure Disorders**

Tegaserod has been associated with seizure disorders, and it is important to monitor patients for any signs of seizures.

**Drug-Drug Interactions**

Tegaserod may interact with other drugs, and it is important to monitor patients for any signs of adverse effects.

**Potentially Life-threatening Events**

Tegaserod has been associated with potentially life-threatening events, and it is important to monitor patients for any signs of these events.

**Contraindications**

Tegaserod is contraindicated in patients with known hypersensitivity to tegaserod or any of its components.

**Warnings and Precautions**

Tegaserod has been associated with adverse effects, and it is important to monitor patients for any signs of adverse effects.

**Reproduction Studies**

Reproduction studies have been conducted in rats and rabbits, and there was no evidence of fetal toxicity. However, tegaserod should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.