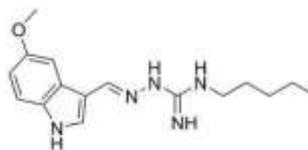


Rx TEGASEROD

(Tegaserod is an oral medication for the treatment of constipation)



GENERIC NAME: tegaserod

DRUG CLASS AND MECHANISM

Tegaserod is an oral medication for the treatment of constipation and constipation-predominant irritable bowel syndrome (IBS) in women. IBS is a chronic gastrointestinal disorder characterized by recurrent abdominal pain or discomfort and altered bowel function which may be either constipation or diarrhea. As many as 20% of American adults may suffer from IBS.

Contractions of the intestinal muscles, primarily those of the colon, control the movement of food through the intestine. In constipated patients, there are fewer contractions than in persons without constipation. An important factor that controls the contractions is serotonin. Serotonin is a chemical manufactured by nerves in the intestine. It is released by the nerves and then travels and binds to receptors on the surface of nearby nerves. It is a "neurotransmitter," a chemical messenger, that is, a chemical that nerves use to communicate with each other. When it binds to receptors on the nerves that control contractions of the intestinal muscles, serotonin can either promote or prevent contractions depending on the type of receptor it binds to. Binding to some types of receptors causes contractions, and binding to other types of receptors blocks contractions.

The serotonin 5-HT₄ receptor is a receptor that prevents contractions when serotonin binds to it. Tegaserod blocks the 5-HT₄ receptor and prevents serotonin from binding to it. As a result, contractions increase. The increased contractions speed the transit of digesting food and reverse the constipation. In addition, tegaserod reduces the sensitivity of the intestinal pain-sensing nerves and can thereby reduce the perception of pain. Tegaserod was approved by the FDA in July, 2002.

PRESCRIPTION: Yes

PREPARATIONS: White, round tablets of 2 and 6 mg.

PRESCRIBED FOR

Tegaserod is used for the short-term treatment of women with IBS whose primary bowel symptom is constipation. It also is approved for the treatment of chronic, idiopathic constipation in men and women less than 65 years of age.

DRUG INTERACTIONS

There are no known drug interactions with tegaserod. Other drugs that increase intestinal contractions will likely lead to more diarrhea if used together with tegaserod.

USES

This medication is used to treat irritable bowel syndrome (IBS) in women who have constipation as a major symptom. Tegaserod relieves constipation by shortening the time stool remains in the bowel, reducing stomach pain and bloating. This medication should not be used to treat IBS in women who have diarrhea as their major symptom, or if you currently have diarrhea or a history of frequent diarrhea. This medication has not been shown to work in men with IBS.

HOW TO USE

Take this medication by mouth, usually twice daily before meals; or as directed by your doctor. Take this medication for 4 to 6 weeks. If you symptoms improve, your doctor may recommend a second 4 to 6 weeks of treatment.

SIDE EFFECTS

Headache or joint pain may occur. If any of these effects persist or worsen, notify your doctor promptly. If diarrhea occurs, it may be only temporary during the first week of treatment. If it occurs, your doctor may recommend that you drink plenty of liquids to avoid becoming dehydrated. If the diarrhea does not resolve on its own after 2 days or if you feel very weak, have severe cramping, dizziness/lightheadedness/fainting, or irregular heartbeats, stop tegaserod and tell your doctor immediately. If you experience different or suddenly worsening stomach/abdominal pain compared to your regular IBS symptoms, with or without bloody stools, stop taking this medication and tell your doctor immediately. This could be a sign of a rare but serious intestinal problem (ischemic colitis). An allergic reaction to this drug is unlikely, but seek

immediate medical attention if it occurs. Symptoms of an allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

DOSING

The usual dose of tegaserod is 6 mg twice daily, most frequently for 4 to 12 weeks. Tegaserod can be taken with or without food. Older persons do not require lower doses than younger persons.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: severe diarrhea and severe headache.

PREGNANCY

No ill effects were seen in the fetuses of pregnant rats given 15 times the human dose and rabbits given 50 times the human dose of tegaserod (on a per-weight basis). Nevertheless, there are no adequate studies of tegaserod in pregnant women. Therefore, physicians must weight the potential benefit of giving tegaserod during pregnancy against the unknown risk.

PRECAUTIONS

This medication is not recommended for use if you have the following medical conditions: severe kidney disease, moderate to severe liver disease, a history of certain stomach disorders (e.g., bowel obstruction, symptomatic gallbladder disease, suspected sphincter of Oddi dysfunction, or abdominal adhesions). Tell your doctor your medical history, especially of: current or repeat episodes of diarrhea or stomach/abdominal pain, and of any allergies you may have. Tell your doctor if you are pregnant before using this medication. Tegaserod should be used during pregnancy only if clearly needed. It is not known whether this drug passes into breast milk. Breast-feeding while using this medication is not recommended. Consult your doctor before breast-feeding.

STORAGE

Store at room temperature (77 degrees F or 25 degree C) away from light and moisture. Brief storage between 59 and 86 degrees F (15 and 30 degrees C) is permitted. Do not freeze.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



Taj Group of Companies ^{INDIA}

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91,
(0)22 - 26374592/93 91 - (0)22 - 30601000,
Fax : 91-(0)22-26341274

Revised November 2010