

Medication Guide
ZELNORM™ (ZEL-norm)
(tegaserod) tablets, for oral use

What is the most important information I should know about ZELNORM?

ZELNORM can cause serious side effects, including:

- **Major heart (cardiovascular) events.** Major cardiovascular events such as stroke, heart attack, and death from stroke or heart attack have happened in adults taking ZELNORM who had an increased risk of having a cardiovascular event.

Risk factors that increase your risk of a major cardiovascular event include:

- o currently smoke
- o high blood pressure or your blood pressure is controlled with medicine that lowers your blood pressure
- o high blood cholesterol levels or your blood cholesterol levels are controlled with medicine that lowers your blood cholesterol levels
- o have or have had diabetes mellitus
- o age 55 years or older
- o obesity

Talk to your healthcare provider about risk factors you may have for a major cardiovascular event before you start taking ZELNORM.

Get emergency medical help right away if you have signs or symptoms of a heart attack, stroke, mini stroke (transient ischemic attack or TIA) or angina (chest pain that happens because your heart is not getting enough oxygen), including:

- chest pain that may spread to the arms, neck, jaw, back, or stomach area (abdomen)
- feeling sweaty
- shortness of breath
- feeling sick or vomiting
- sudden numbness or weakness, especially on one side of the body
- severe headache or confusion
- problems with vision, speech, or balance

Tell your healthcare provider right away if you are told that you have narrowing in the blood vessels that carry blood to your heart (coronary artery disease).

- **Inflammation and injury of the intestines caused by reduced blood flow to the intestines (ischemic colitis).** Ischemic colitis and other problems of the intestines caused by reduced blood flow to the intestines, that sometimes required hospitalization, have happened in some people taking ZELNORM. Stop taking ZELNORM and call your healthcare provider or get medical help if you have symptoms of ischemic colitis such as bleeding from your rectum, bloody diarrhea, or new or worsening stomach-area (abdominal) pain.

- **Loss of body fluids caused by diarrhea.** Diarrhea is a common side effect of ZELNORM, and it can sometimes be severe. Severe diarrhea can result in the loss of too much fluid from your body, low blood pressure, and fainting (loss of consciousness). Some people who had severe diarrhea during treatment with ZELNORM were hospitalized due to loss of too much body fluid. Stop taking ZELNORM and call your healthcare provider right away if you have severe diarrhea, especially if you also feel lightheaded, dizzy, or you faint.

- **Suicidal thoughts and behavior.** ZELNORM may increase the risk of suicidal thoughts and behavior. You, your caregiver, and your family should monitor you for changes in behavior. If you have any new or worsening symptoms of depression, unusual changes in mood or behavior, begin to have suicidal thoughts or behavior, or thoughts of self-harm, stop taking ZELNORM right away and tell your healthcare provider.

What is ZELNORM?

ZELNORM is a prescription medicine used for the treatment of adult women less than 65 years of age who have irritable bowel syndrome with constipation (IBS-C).

It is not known if ZELNORM is safe and effective in men with IBS-C.

It is not known if ZELNORM is safe and effective in children.

Do not take ZELNORM if you:

- have had a heart attack, stroke, transient ischemic attack or TIA, or angina.
- have had inflammation and injury of the intestines caused by reduced blood flow to the intestines (ischemic colitis).
- have severe kidney problems or end-stage kidney disease.
- have moderate or severe liver problems.
- have had an intestinal blockage (bowel obstruction), gallbladder problems that caused symptoms, or scar tissue that formed between the tissues of the abdomen and other organs in the abdomen.
- have or may have had a problem with the muscular valve that controls the flow of digestive juices (bile and pancreatic juice) to the first part of your intestine (sphincter of Oddi).
- are allergic to tegaserod.

Before taking ZELNORM, tell your healthcare provider about all of your medical conditions, including if you:

- currently smoke.
- have or have had high blood pressure or are taking medicine to lower your blood pressure.
- have or have had high blood cholesterol levels or are taking medicine to lower your blood cholesterol levels.
- have or have had diabetes.
- are having diarrhea or have diarrhea often.
- are pregnant or plan to become pregnant. It is not known if ZELNORM will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ZELNORM passes into your breast milk. **You should not breastfeed if you take ZELNORM.**

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take ZELNORM?

- Take ZELNORM exactly as your healthcare provider tells you to take it.
- The usual dose of ZELNORM is 1 tablet 2 times each day, taken by mouth.
- Take ZELNORM at least 30 minutes before a meal.
- If you take too much ZELNORM, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of ZELNORM?

ZELNORM can cause serious side effects, including:

- See “**What is the most important information I should know about ZELNORM?**”

The most common side effects of ZELNORM are:

- headache
- stomach-area (abdominal) pain
- nausea
- gas
- indigestion
- dizziness

These are not all the possible side effects of ZELNORM.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ZELNORM?

- Store ZELNORM at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect ZELNORM from moisture.

Keep ZELNORM and all medicines out of the reach of children.

General information about the safe and effective use of ZELNORM.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZELNORM for a condition for which it was not prescribed. Do not give ZELNORM to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about ZELNORM that is written for health professionals.

What are the ingredients in ZELNORM?

Active ingredient: tegaserod

Inactive Ingredients: colloidal silicon dioxide, crospovidone, glyceryl behenate, hypromellose, and lactose monohydrate

SLOAN

P H A R M A™

Distributed by: US WorldMeds, LLC Louisville, KY 40241

Under License from Sloan Pharma S.a.r.l.

Sloan Pharma S.a.r.l. is the exclusive licensee and US WorldMeds, LLC is the distributor of ZELNORM in the United States and Its territories. ©2019. ZELNORM is a trademark of Sloan Pharma S.a.r.l.

For more information, call 1-855-697-9232.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: March 2019