



Alfasigma USA Acquires ZELNORM™ (tegaserod) for Reintroduction to the US Market

- Alfasigma USA has acquired the brand ZELNORM (tegaserod), a treatment for IBS-C, from Sloan Pharma S.à r.l.
- In early 2019, ZELNORM was approved for reintroduction by the FDA for the treatment of adult women less than 65 years of age with IBS-C.
- Alfasigma USA plans to relaunch the brand in the United States, making ZELNORM available by prescription in the coming weeks.

Bedminster, NJ, July 8, 2019 – [Alfasigma USA, Inc.](#) today announced it has acquired the brand ZELNORM, a prescription pharmaceutical treatment for irritable bowel syndrome with constipation (IBS-C), from Sloan Pharma S.à r.l., a subsidiary of US WorldMeds Holdings, LLC. Plans to relaunch ZELNORM in the United States are currently underway.

Originally approved in 2002 as the first prescription medication for IBS-C, ZELNORM was voluntarily withdrawn from the market in 2007 due to concerns regarding possible cardiovascular risk; however, the drug has remained available in the US through an expanded access program authorized by the FDA. In early 2019, ZELNORM was approved by the FDA for reintroduction for use in adult women (<65 years of age) with IBS-C. The approval to reintroduce ZELNORM came after a thorough safety review by the FDA and an FDA-assembled Gastrointestinal Drugs Advisory Committee (GIDAC). The evaluation consisted of a review of the clinical data from 29 placebo-controlled trials and post-marketing treatment outcomes data.

“We are excited by the opportunity to make ZELNORM once again available to healthcare providers to treat adult women in the US suffering from IBS-C,” said Bryan Downey, President and Chief Executive Officer at Alfasigma USA. “There is a substantial unmet need for IBS-C therapies with reliable efficacy, comparable safety, and that help address the debilitating pain and bloating associated with the disease. We look forward to making this effective IBS-C treatment available to the patients who may benefit the most.”

ZELNORM is the only selective serotonin-4 (5-HT₄) receptor agonist approved to treat IBS-C. It provides a unique treatment by targeting the 5-HT₄ receptor at multiple neurons (sensory, motor, secretory motor) and smooth muscle cells in the gastrointestinal tract to induce contraction and relaxation, and decrease pain signaling.

“We believed in the value of ZELNORM and invested a tremendous amount of time and effort to receive FDA approval for reintroduction and support for the revised indication in March, 2019. The commercial capabilities of Alfasigma USA make it the right organization to reintroduce ZELNORM to the US market,” stated Hans van Zoonen, Manager of the Switzerland Branch of Sloan Pharma, S.à r.l.

IBS is prevalent in 7-21% of adults worldwide and in 5-9% of US adults. Its prevalence has increased over the past several decades and is particularly high in adult female patients over 50 years of age.¹⁻⁵ IBS is associated with substantially impaired quality of life, including effects on lifestyle, daily activities, and sleep, as well as work absenteeism.

According to Mr. Downey, “The reintroduction of ZELNORM is a first step in fulfilling our promise to find prescription pharmaceutical opportunities for Alfasigma in the US. With ZELNORM, our Alfasigma corporate slogan ‘Pharmaceuticals with Passion’ is now as meaningful in the US as it is globally.”

Alfasigma USA looks forward to making ZELNORM available by prescription in the coming weeks. For more information, please see the Medication Guide and full Prescribing Information for ZELNORM at www.zelnormus.com.

About Alfasigma USA, Inc.

Alfasigma USA, Inc. is the American affiliate of Alfasigma, a leading Italian pharmaceutical company. Alfasigma is present in more than 90 countries, with a workforce of around 3,000 people and 5 manufacturing plants. Alfasigma USA, Inc. distributes a portfolio of prescription nutritional products to help individuals who are suffering from GI disorders (VSL#3[®]), major depressive disorder (DEPLIN[®]), diabetic peripheral neuropathy (METANX[®]), and mild cognitive impairment (CerefolinNAC[®]). With the acquisition of ZELNORM[™], Alfasigma USA is building on their commitment to making ‘Pharmaceuticals with Passion’ in the US. For more information, please visit www.alfasigmausa.com or email info@alfasigma.com.

About Sloan Pharma, S.à r.l.

Sloan Pharma, S.à r.l. is a subsidiary of US WorldMeds Holdings, LLC, a specialty pharmaceutical company whose products are making a difference in the lives of the patients and communities it serves. US WorldMeds takes an agile and personal approach to pharmaceuticals – pioneering research and product development in therapeutic areas that desperately need new solutions. Headquartered in Louisville, Kentucky, US WorldMeds has global presence and nearly 20 years of experience in the development, licensure, and commercialization of unique products. For more information about US WorldMeds, visit <https://www.usworldmeds.com/>.

ZELNORM Indications and Usage:

ZELNORM is indicated for the treatment of adult women less than 65 years of age with irritable bowel syndrome with constipation (IBS-C).

ZELNORM Important Safety Information

- Do not take ZELNORM if you:
 - have had a heart attack, stroke, transient ischemic attack (TIA), angina, inflammation and injury of the intestines caused by reduced blood flow to the intestines (ischemic colitis), intestinal blockage (bowel obstruction), gallbladder problems that caused symptoms, or scar tissue that formed between the tissues and other organs in the abdomen;
 - have severe kidney problems or end-stage kidney disease, or moderate or severe liver problems;
 - have or may have had a problem with the muscular valve that controls the flow of digestive juices to the first part of your intestine (sphincter of Oddi); or
 - are allergic to tegaserod.
- ZELNORM can cause serious side effects. Major cardiovascular events, such as stroke, heart attack, and death have happened in adults taking ZELNORM who had an increased risk of a cardiovascular event. Talk to your healthcare provider about risk factors you may have before you start taking ZELNORM and get emergency medical help right away if you have signs or symptoms of a heart attack, stroke, mini stroke (TIA), or angina (chest pain caused by your heart not getting enough oxygen).
- Ischemic colitis and other problems of the intestines have happened in some people taking ZELNORM. Stop taking ZELNORM and get medical help if you have symptoms such as rectal bleeding, bloody diarrhea, or new or worsening stomach-area (abdominal) pain.
- Diarrhea is a common side effect of ZELNORM, and it can sometimes be severe. Stop taking ZELNORM and call your healthcare provider right away if you have severe diarrhea, especially if you also feel lightheaded or dizzy, or if you faint.
- 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.
- Tell your healthcare provider if you are pregnant or plan to become pregnant. It is not known if ZELNORM will harm your unborn baby.
- Tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if ZELNORM passes into breast milk. You should not breastfeed if you take ZELNORM.
- The most common side effects of ZELNORM are headache, abdominal pain, nausea, diarrhea, flatulence, dyspepsia, and dizziness.



To report SUSPECTED ADVERSE REACTIONS or product complaints, contact Alfasigma USA at 855-697-9232. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information and Medication Guide at www.zelnormus.com.

1. Hungin AP, et al. *Aliment Pharmacol Ther*. 2003;17(5):643-50.
2. Halder SL, et al. *Gastroenterology*. 2007;133(3):799-807.
3. Ford AC, et al. *Am J Gastroenterol*. 2008;103(5):1229-39.
4. Lovell RM, Ford AC. *Clin Gastroenterol Hepatol*. 2012;10(7):712-21.e4.
5. Mearin F, et al. *Gastroenterology*. 2016. doi:10.1053/j.gastro.2016.02.031 [Epub ahead of print].