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On behalf of Alfasigma USA, Inc.

Press Release

ZELNORM® (tegaserod) Notice of Withdrawal from Market

Covington, LA, June 30, 2022 – Alfasigma USA, Inc. announces the withdrawal of the NDA for ZELNORM® (tegaserod) effective June 30th. Alfasigma USA, Inc. will no longer make the product available in the US marketplace.

Please know that this decision was not made lightly nor was it based on product efficacy, safety or because of an imposed recall. Our decision to remove ZELNORM® (tegaserod) from the market is strictly a business decision.

Patients will continue to have access to ZELNORM® (tegaserod) for as long as the existing supply of product remains in the trade channel. Alfasigma USA, Inc. urges patients and Health Care Providers to discuss alternative therapies that will meet patient needs.

Important Safety Information
ZELNORM® ® IMPORTANT SAFETY INFORMATION (ISI)

Indication
ZELNORM® (tegaserod) is a serotonin-4 (5-HT4) receptor agonist indicated for the treatment of adult women less than 65 years of age with irritable bowel syndrome with constipation (IBS-C).

Warnings and Precautions

Cardiovascular Ischemic Events, Including Major Adverse Cardiovascular Events (MACE): Stroke, MI, and cardiovascular death have been reported in adults taking ZELNORM® who had an increased risk of developing an adverse cardiovascular event based on their medical history.
Female patients less than 65 years of age should be assessed for a history of cardiovascular disease and cardiovascular risk factors prior to treatment with ZELNORM® (R).
Discontinue ZELNORM® (R) in patients who experience an MI, stroke, TIA, or angina. Evaluate the risks and benefits of continued use of ZELNORM® (R) in patients who develop evidence of cardiovascular ischemic heart disease (e.g., coronary artery disease) and/or experience changes in health status that could increase cardiovascular risk during treatment with ZELNORM® (R).

Ischemic Colitis: Ischemic colitis and other forms of intestinal ischemia have been reported postmarketing in patients receiving ZELNORM® (R). Discontinue ZELNORM® (R) in patients who develop symptoms of ischemic colitis, such as rectal bleeding, bloody diarrhea, or new or worsening abdominal pain.

Volume Depletion Associated with Diarrhea: In postmarketing experience, serious consequences of diarrhea including hypovolemia, hypotension, and syncope have been reported in patients treated with ZELNORM® (R). Avoid use of ZELNORM® (R) in patients who are currently experiencing or frequently experience diarrhea. Instruct patients to discontinue ZELNORM® (R) and contact their healthcare provider if severe diarrhea, hypotension, or syncope occur.

Suicidal Ideation and Behavior: Monitor all ZELNORM® (R)-treated patients for clinical worsening of depression and emergence of suicidal thoughts and behaviors, especially during the initial few months of treatment. Counsel family members and caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Instruct patients to immediately discontinue ZELNORM® (R) and contact their healthcare provider if their depression is persistently worse or they are experiencing emergent suicidal thoughts or behaviors.

Common Adverse Reactions (incidence >2% and greater than placebo)
The most common adverse reactions in 3 placebo-controlled trials of ZELNORM® (R) in female IBS-C patients less than 65 years of age: headache (14% vs 10% placebo), abdominal pain (11% vs 10%), nausea (8% vs 7%), diarrhea (8% vs 3%), flatulence (6% vs 5%), dyspepsia (4% vs 3%), and dizziness (4% vs 3%).

Use in Specific Populations

- **Pregnancy:** Safety and effectiveness not established
- **Lactation:** Breastfeeding not recommended
- **Pediatric use:** Safety and effectiveness not established
- **Geriatric use:** Not indicated for patients 65 years of age and older
- **Severe renal conditions:** Contraindicated
- **Moderate to severe hepatic conditions:** Contraindicated

For more information, please see the Medication Guide and full Prescribing Information for ZELNORM® (R) at www.ZELNORM® (R)us.com.

In order to assist Alfasigma USA, Inc. in monitoring safety, we encourage all healthcare professionals to report any adverse events to Alfasigma USA, Inc. at 1-844-639-9726 or to the FDA at 1-800-FDA-1088 or online at http://www.fda.gov/Safety/MedWatch/ .

If you have any additional questions, please contact Alfasigma USA, Inc. Medical Information at 1-844-639-9726 between the hours of 8:00 a.m. and 5:00 p.m. EST.

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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®) (ZELNORM®), major depressive disorder (DEPLIN®), diabetic peripheral neuropathy (METANX®), and mild cognitive impairment (CerefolinNAC®).

Alfasigma USA, Inc. 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.

ALUSA-00646