Pfizer Logo

Pfizer Inc and Progenics Alert Physicians and Patients to Information Related to Triad Group Alcohol Prep Products Included In U.S. RELISTOR Kit Packaging

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(BUSINESS WIRE)--Pfizer Inc and Progenics Pharmaceuticals, Inc. have learned of a United States market recall of alcohol prep pads and swabs manufactured by the Triad Group. In the interest of patient safety, Pfizer and Progenics are alerting U.S. patients and physicians to Triad's recall. Triad® Alcohol Prep Pads are packaged for use with the kit presentation of RELISTOR® (methylnaltrexone bromide) Subcutaneous Injection in the U.S. The RELISTOR vial and other components of the kit are not affected by the defective Triad alcohol pad. RELISTOR sold in single vials also is unaffected by this recall.

Pfizer and Progenics advise patients using the RELISTOR kit not to use the Triad alcohol prep pads included in the RELISTOR packaging for 1 X 7 kits and 1 X 2 starter kits. When preparing to take their RELISTOR injection, patients should use an alcohol prep pad from a company other than Triad, or use a sterile gauze pad with isopropyl alcohol.

Shipments of RELISTOR kits have been suspended until the alcohol pads can be replaced, which will be done as quickly as possible to enable patients to continue to receive RELISTOR. Triad alcohol prep products are not included in RELISTOR sold as single vials or in RELISTOR kits outside of the United States or with other Pfizer medications.

The following information about the recall of Triad alcohol prep products is available on the U.S. Food and Drug Administration's web site:

Triad press release: http://www.fda.gov/Safety/Recalls/ucm239219.htm
Safety information:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm239319.htm
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Patients with questions about RELISTOR should consult their pharmacist or healthcare provider, or call Pfizer Medical Information at 1-800-438-1985. RELISTOR is manufactured and marketed by Pfizer under a licensing agreement with Progenics.

About RELISTOR

RELISTOR Subcutaneous Injection is approved in the United States for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. The use of RELISTOR beyond four months has not been studied. The drug is

also approved for use in over 50 countries worldwide, including in the European Union, Canada, Australia and Brazil. Applications in additional countries are pending. In the 27 member states of the E.U., as well as Iceland, Norway and Liechtenstein, RELISTOR is approved for the treatment of OIC in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. In Canada, the drug is approved for the treatment of opioid-induced constipation in patients with advanced illness, receiving palliative care. When response to laxatives has been insufficient, RELISTOR should be used as an adjunct therapy to induce a prompt bowel movement. RELISTOR is the brand name under which methylnaltrexone is marketed outside Japan by Wyeth, a wholly-owned subsidiary of Pfizer.

Important Safety Information for RELISTOR

- RELISTOR is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction
- If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their physician
- Rare cases of gastrointestinal (GI) perforation have been reported in advanced illness patients. Use RELISTOR with caution in patients with known or suspected lesions of the GI tract
- Use of RELISTOR has not been studied in patients with peritoneal catheters
- The most common adverse reactions reported with RELISTOR compared with placebo in clinical trials were abdominal pain (28.5% vs. 9.8%), flatulence (13.3% vs. 5.7%), nausea (11.5% vs. 4.9%), dizziness (7.3% vs. 2.4%), diarrhea (5.5% vs. 2.4%), and hyperhidrosis (6.7% vs. 6.5%)
- Safety and efficacy of RELISTOR have not been established in pediatric patients

RELISTOR full Prescribing Information for the U.S. is available at www.relistor.com.

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