Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Apace Packaging LLC Issues Voluntary Nationwide Recall of Acyclovir (Lot 19900) Due to Product Mix-up

For Immediate Release

February 13, 2018

Contact

Consumers

270-434-2722

Announcement

View Product Photos

Apace Packaging LLC is voluntarily recalling one lot of Acyclovir Tablet, USP, 400mg, 50ct Unit Dose, NDC# 50268-061-15, Lot Number 19900, to the Retail level. These products have been recalled due to a product mix-up. A small number of blister cards containing Acyclovir Tablets, 400mg, UD Blister Cards may potentially also include Torsemide, 20mg, Tablets.

Missing a dose of Acyclovir Tablets could cause a reactivation of a virus being treated. Unintentional dosing of Torsemide, 20mg, Tablets could cause excessive urination. Serious adverse events reported in the clinical studies, for which a drug relationship could not be excluded, were atrial fibrillation, chest pain, diarrhea, digitalis intoxication, gastrointestinal hemorrhage, hyperglycemia, hyperuricemia, hypokalemia, hypotension, hypovolemia, shunt thrombosis, rash, rectal bleeding, syncope, and ventricular tachycardia. To date, Apace Packaging LLC has not received any reports of adverse events related to this recall. Acyclovir Tablet, USP, 400mg 50ct Unit Dose (NDC# 50268-061-15) is used for the acute treatment of herpes zoster (shingles), for the initial treatment and management of recurrent episodes of genital herpes, and for the treatment of chickenpox. Torsemide, 20mg, Tablets are used for the treatment of edema and hypertension. The product is packaged in 50-count hospital unit dose cartons (10 unit doses per card, 5 cards per carton). The affected lot of Acyclovir 400mg Tablet is Lot 19900 with an expiration date of 05/2019. The subject product was fully distributed to R&S Northeast, and then further distributed nationwide.

Apace Packaging LLC has notified its distributors and customers by email and is arranging for return of all recalled product. Distributors that have any of the subject product which is being recalled should contact Customer Service at AvKARE, Inc. at 931-292-6222 to arrange for the return of the product.

Consumers with questions regarding this recall can contact Apace Packaging by 270-434-2722 Monday-Friday (8am – 4pm CST). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/MedWatch/report.htm)**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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