COMPANY ANNOUNCEMENT

Sagent Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Levetiracetam Injection, USP Due to Lack of Sterility Assurance

Summary

Company Announcement Date:

November 19, 2021

FDA Publish Date:

November 22, 2021

Product Type:

Drugs

Reason for Announcement:

Lack of sterility assurance

Company Name:

Sagent Pharmaceuticals, Inc.

Brand Name:

Sagent

Product Description:

Levetiracetam Injection

Company Announcement

CHICAGO, IL – November 19, 2021 - Sagent Pharmaceuticals, Inc. today announced the voluntary nationwide recall of four lots of Levetiracetam Injection, USP, to the user level. The lack of container closure integrity, found in reserve sample vials may result in a non-sterile product.

Risk Statement: Intravenous administration of a product intended to be sterile that is not sterile could result in serious systemic infections which may be life threatening. To date, Sagent has not received reports of any product complaints or adverse events associated with this issue.

Levetiracetam Injection, USP 500 mg per 5 mL, is used in the treatment of certain types of seizures and is packaged in a 5mL single-does vial. The Levetiracetam Injection, USP, label and affected lot numbers with Expiration Dates and NDC number can be found in the table below. Product was distributed Nationwide from March to November 2021.

Product	Lot Number	Expiration Date	NDC Number	Distribution Dates
Levetiracetam Injection, USP	B0G85VB	Jun-2022	25021-780-05	May 2021 - August 2021
	B0K88VA	Sep-2022		March 2021 - November 2021
	B0K89VA	Sep-2022		August 2021 - November 2021
	B1G194A	Jun-2023		October 2021

Sagent Pharmaceuticals, Inc. is notifying customers by fax, email, FedEx, and/or certified mail, which includes arrangements for return of all recalled product. Customers that have Levetiracetam Injection, USP 500mg per 5 mL, which is being recalled, have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of, and return as directed the recalled lots of product. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this product recall. Healthcare/distributors/retailers that have product which is being recalled should stop using product and return the recalled product. The necessary form to document product information, as well as other information regarding this recall, is available at www.Sagentpharma.com (//www.Sagentpharma.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Consumers or healthcare workers with any questions regarding this recall can contact the customer call center (866) 625-1618 M-F, 8am-7pm CST. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)

- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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.

Company Contact Information

Consumers:

Customer Call Center

(866) 625-1618

Product Photos

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