Company Announcement

Sagent Pharmaceuticals Issues Voluntary Nationwide Recall of Methylprednisolone Sodium Succinate for Injection, USP, 40mg, 125mg, and 1g Due to High Out of Specification Impurity Results

For Immediate Release

March 5, 2018

Contact

Consumers

(866) 625-1618

Announcement

View Product Photos

Sagent Pharmaceuticals, Inc. today announced the voluntary nationwide recall of ten lots of Methylprednisolone Sodium Succinate for Injection, USP, 40mg, 125mg, and 1g. A detailed listing of products and lots is listed below. These products were manufactured by Gland Pharma Ltd. and distributed by Sagent Pharmaceuticals. Sagent has initiated this voluntary recall of Methylprednisolone Sodium Succinate for Injection, USP to the user level due to the discovery of high out of specification impurity results detected during routine quality testing of stability samples for two lots. This impurity has not yet been identified.

An elevated impurity has the potential to decrease effectiveness of the product in patients. To date, Sagent is not aware of any adverse patient events resulting from the use of the subject product lots.

Methylprednisolone Sodium Succinate for Injection, USP is an anti-inflammatory glucocorticoid indicated for a number of conditions, including but not limited to: allergic states, dermatologic diseases, endocrine disorders, gastrointestinal diseases, hematologic disorders, miscellaneous (trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy), neoplastic diseases, nervous system, ophthalmic diseases, renal diseases, respiratory diseases, and rheumatic disorders. The product is supplied in 5 ml, 10 ml, and 30 ml glass tubular vials. The lot numbers being recalled were distributed to hospitals, wholesalers and distributors nationwide from April 2017 through February 2018.

Product	Lot Numbers	Expiration Date	NDC Number	Distribution Dates
Methylprednisolone Sodium Succinate for Injection, USP, 40mg	AJM601 AJM701 AJM702	Jul-2018 Dec-2018 Dec-2018	25021-807-05 25021-807-05 25021-807-05	Apr –Aug 2017 Aug – Nov 2017 Nov 2017 – Feb 2018
Methylprednisolone Sodium Succinate for Injection, USP, 125mg	AJN601 AJN701 AJN702	Jun-2018 Dec-2018 Dec-2018	25021-808-10 25021-808-10 25021-808-10	Apr – Oct 2017 Aug 2017 – Jan 2018 Dec 2017 – Feb 2018
Methylprednisolone Sodium Succinate for Injection, USP, 1g	AJP701 AJP702 AJP601 AJP703	Dec-2018 Dec-2018 Jul-2018 Aug-2019	25021-810-30 25021-810-30 25021-810-30 25021-810-30	Sep – Dec 2017 Dec 2017 – Feb 2018 Apr – Sep 2017 Jan – Feb 2018

Customers are being notified by fax, email, FedEx, and/or certified mail that includes arrangements for return of all recalled product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lot 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. The necessary form by which to document this information as well as other information regarding this recall is available at **www.Sagentpharma.com (http://www.Sagentpharma.com)**.

Customers or consumers with any questions about returning unused product should be directed to the customer call center at (866) 625-1618 M-F 8am-7pm CST. Healthcare workers who have medical questions about Methylprednisolone Sodium Succinate for Injection, USP may contact Medical Affairs (866-625-1618, Option 3) M-F 8am-5pm CST. Consumers 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: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form 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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Product Photos

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