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COMPANY ANNOUNCEMENT

Par Pharmaceutical, Inc. Issues Voluntary Nationwide Recall of One Lot of Mycophenolate Mofetil for Injection, USP Due to the Presence of a Glass Fragment Observed in One Vial of Reconstituted Product

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.

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Summary

Company Announcement Date:

May 01, 2019

FDA Publish Date:

May 03, 2019

Product Type:

Drugs
Generic Drugs

Reason for Announcement:

Device & Drug Safety, Potential Foreign Material

Company Name:

Par Pharmaceutical, Inc.

Brand Name:

Par Pharmaceutical

Product Description:

Mycophenolate Mofetil for injection

Company Announcement

Endo International plc, announced today that one of its operating companies, Par Pharmaceutical, Inc., is voluntarily recalling one lot of Mycophenolate Mofetil for Injection, USP to the hospital and retail pharmacy level. One vial of product was observed containing a glass fragment after reconstitution.

The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening. To date, Par Pharmaceutical, Inc. has not received any reports of adverse events related to this recall.

Mycophenolate Mofetil for Injection, USP is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac or hepatic transplants. Mycophenolate Mofetil for Injection, USP should be used concomitantly with cyclosporine and corticosteroids. The affected Mycophenolate Mofetil for Injection, USP includes lot AD812, expiry 09/2020. The product, manufactured for Par Pharmaceutical, Inc. by Gland Pharma Limited, is packaged in cartons of 4 single use vials with NDC 42023-172-04. Mycophenolate Mofetil for Injection, USP, lot AD812 was distributed nationwide in the U.S. to wholesale distribution locations between January 23, 2019, and February 11, 2019.

Vials from the affected lot bear this label:

Par Pharmaceutical, Inc. is providing written notification to national wholesale accounts and direct customer locations that have received the affected lot and is arranging for return of all recalled product through Inmar, Inc. Wholesale distributors, retail pharmacies, and hospital pharmacies that have the product being recalled should immediately stop further distribution and use of vials from Lot AD812 and return any unused product by following the instructions below:

- Please contact Inmar, Inc. either by phone at 1-800-967-5952, extension 1 (Monday through Friday between 9 am and 5 pm ET), or by email at rxrecalls@inmar.com (mailto:rxrecalls@inmar.com) to obtain return authorization labels and return shipping instructions.
- Upon contacting Inmar, Inc. please be prepared to provide proof of purchase to receive reimbursement for returned product.

Wholesalers, retailers, pharmacies, and consumers with questions regarding this recall can contact Inmar, Inc. either by phone at 1-800-967-5952, extension 1 (Monday through Friday between 9 am to 5 pm ET), or by email at rxrecalls@inmar.com (mailto:rxrecalls@inmar.com). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug 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 (/node/360543)
- Regular Mail or Fax: Download form (/node/360547) 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:

Inmar, Inc

1-800-967-5952, extension 1

rxrecalls@inmar.com (mailto:rxrecalls@inmar.com)

Media:

Heather Zoumas-Lubeski

(484) 216-6829

Product Photos

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