COMPANY ANNOUNCEMENT

Fresenius Kabi's Recall of Ketorolac Results In QuVa Pharma® Recall of Compounded Sterile Product (R.E.C.K.)

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.

Read Announcement

Summary

Company Announcement Date:

April 23, 2020

FDA Publish Date:

April 27, 2020

Product Type:

Drugs

Reason for Announcement:

presence of particulate matter

Company Name:

QuVa Pharma, Inc.

Brand Name:

QuVa

Product Description:

R.E.C.K. (Ropivacaine, Epinephrine, Clonidine, Ketorolac) 50 ml in Sodium Chloride-60 ml BD syringe

Company Announcement

SUGAR LAND, Texas, April 23, 2020 -- QuVa Pharma, Inc. confirms that is working with the U.S. Food and Drug Administration, and voluntarily recalling all lots of R.E.C.K. (Ropivacaine, Epinephrine, Clonidine, Ketorolac) 50 ml in Sodium Chloride-60 ml BD syringe that were prepared using sterile Ketorolac being recalled by Fresenius Kabi. Fresenius Kabi recalled multiple lots of Ketorolac on April 20, 2020 due to the presence of particulate matter found in the reserve sample vials.

QuVa has reached out to all hospital pharmacy customers who purchased product from the lots affected and has asked them to: quarantine anything that is in stock to prevent use in direct patient care; complete a return response form to capture the amount of unused product; and return the finished goods to QuVa for destruction.

Listed below are the recalled lots distributed directly to hospital pharmacies between February 13, 2020 and April 21, 2020.

Product Description	Product Code	Lot Numbers
R.E.C.K. (Ropivacaine, Epinephrine, Clonidine, Ketorolac) 50ml in Sodium Chloride—60ml BD syringe	70092-1433-50	30009563, 30009539, 30009489, 30009412, 30009413, 30009411, 30009410, 30009388, 30009387, 30009228, 30009227, 30009139, 30009138, 30009074, 30009073, 30008949, 30008859, 30008861, 30008554, 30008198, 30008721

Customers with questions about the recall can email QuVa at QuVaRecallApril2020@Quvapharma.com (mailto:QuVaRecallApril2020@Quvapharma.com) or contact QuVa Pharma Customer Service at **888.339.0874**

About QuVa Pharma, Inc.

QuVa Pharma is a nationally recognized, industry-leading, cGMP compliant FDA registered 503B manufacturing platform and partner of choice for compliance-oriented healthcare facilities looking to ensure a quality, safe, and consistent supply of medications. The company offers a robust portfolio of ready-to-administer products across pain management, anesthesia and OR, anti-infectives, labor and delivery, cardiovascular, and general medicine therapeutic classes. All products are distributed only once sterility and potency testing are successfully completed, and with validation supporting appropriate Beyond Use Dating (BUD). The company is committed to having a patient-safety orientation, leading compliance and safety standards, and being collaborative and transparent in service of our customers. For more information, please visit www.quvapharma.com (www.quvapharma.com) or follow QuVa on LinkedIn at https://www.linkedin.com/company/quvapharma-inc-/ (https://www.linkedin.com/company/quvapharma-inc-/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

For media inquiries, please contact: Mike.Scouvart@QuVaPharma.com (mailto:Mike.Scouvart@QuVaPharma.com)

Company Contact Information

Consumers:

888.339.0874

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