SAGENT®

Sagent Pharmaceuticals, Inc.

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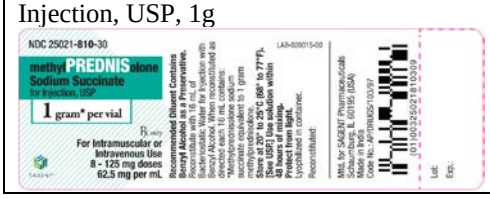
CUSTOMER NOTIFICATION/ RECALL COMMUNICATION

URGENT: METHYLPREDNISOLONE SODIUM SUCCINATE FOR INJECTION, USP, 40MG; METHYLPREDNISOLONE SODIUM SUCCINATE FOR INJECTION, USP, 125MG; and METHYLPREDNISOLONE SODIUM SUCCINATE FOR INJECTION, USP, 1G RECALL

March 5, 2018

Dear Valued Customer:

This letter is to inform you that Sagent Pharmaceuticals, Inc. is voluntarily recalling the following product:

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	April –August 2017 August – November 2017 November 2017 – February 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	April – October 2017 August 2017 – January 2018 December 2017 – February 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	September – December 2017 December 2017 – February 2018 April – September 2017 January – February 2018

This recall is being made with the knowledge of the Food and Drug Administration, and has been initiated due to the discovery of 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 known adverse patient events resulting from the use of the products identified in the table above.

To implement this recall, please take the following actions:

1. Immediately examine your inventory and quarantine product subject to recall.

2. Weigh the product. (Required for generation of call tag)

3. Immediately discontinue distribution of the above listed lot (s). A credit memo will be issued covering the quantity of your product returned.

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4. Return product to :
   DLSS (DOHMEN Life Science Services)
   ATTN: Returns Department
   4580 S. Mendenhall
   Memphis, TN 38141

   NOTE: Return shipment is free of charge. A call tag, a pre-printed, pre-paid return label will be provided to you for product return. Contact Customer Service at 1-866-625-1618, option 1, for a call tag. Wholesalers: No call necessary, just send debit memo via email or fax to: orders@sagentpharma.com or 1-866-821-5358.

5. If you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers should include a copy of this recall notification letter and response form.

6. Please complete and return the enclosed "Customer Recall Return Response Form" as soon as possible and fax the form to us at 1-901-368-6903. The completed form may also be emailed to DDNRegulatory@ddnnet.com.

This recall should be carried out to the **user level**.

Your assistance is appreciated. I apologize for any inconvenience this may cause you.

If you have any questions, please do not hesitate to call our Customer Service at **1-866-625-1618**, M-F 8am – 7pm CST, which was specifically set-up to address any concerns that you may have.

Sincerely,

Michael Hitchingham

Michael Hitchingham
Director, Quality Systems
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