



December 11, 2017

URGENT: VOLUNTARY DEVICE RECALL
Depth of Recall: Wholesaler / Pharmacy / Hospital / Physician Clinics

PMA	Product Description	Lot #	Expiration Date
P940015	Synvisc-One ® (hylan G-F 20)	7RSL021	2020-05-31

To Hospital / Physician Clinics,

This letter is to inform you that Sanofi Genzyme is voluntarily recalling one (1) lot of **Synvisc-One® (hylan G-F20) lot 7RSL021**. No other Synvisc-One or SYNVISIC lots are impacted by this voluntary recall. This product was distributed between October 25, 2017 and November 07, 2017 and our records indicate that you may have received product within this time period.

This is a voluntary product recall due to an ongoing investigation in which subsequent investigational testing revealed the presence of microbial contamination. This voluntary recall is being conducted with the knowledge of the US Food and Drug Administration and we are working with your distributors to ensure that all product in lot 7RSL021 is returned.

Use of this recalled lot may result in a risk of infection and therefore, we are asking that you follow the required actions below to assist us in retrieving any remaining units of this voluntarily recalled lot.

Required Actions:

Patient Management

- **Immediately discontinue use of the Synvisc-One lot number 7RSL021.**
- **Health Care Professionals should treat their patients exposed to lot 7RSL021 in accordance with standard of care, being aware of the potential of a Gram negative infection.**

Product Returns Procedure

- **Return labels will be mailed to you as a part of the product return kit from FedEx Supply Chain Solutions (GENCO Pharmaceutical Services). If you did not receive labels in this product return kit or for information related to the recalled Synvisc-One lot 7RSL021 product returns, please contact FedEx Supply Chain Solutions (GENCO) at 1-855-838-5782.**
- **Check your inventory and return all Synvisc-One lot number 7RSL021 as per the instructions provided below.**

- ***Please complete and return the Business Reply Card whether or not you have remaining syringes to help us determine if all existing stock has been returned. If you prefer to fax this information, the fax number is 1-414-459-8791; email address is recalls@genco.com***
- **Package the syringe(s) that you are returning in a manner to prevent breakage or damage during shipment and return to FedEx Supply Chain Solutions (GENCO) utilizing the prepaid FedEx return shipping label that is enclosed with this letter. Please also include a copy of the included packing slip with your return.**

Return all recalled product to:

**FedEx Supply Chain Solutions
Genco Pharmaceutical Services
6101 North 64th Street
Milwaukee, WI 53218**

Sanofi Genzyme will issue you a credit upon receipt of the voluntary recalled product.

All medical and clinical questions should be directed to Sanofi Medical Information Services in the U.S. at 1-800-633-1610, option 1.

General Questions about the voluntary product recall should be directed to Sanofi U.S. Customer Service at 1-800-633-1610 option 7 then 4.

Sanofi Genzyme is fully committed to maintaining the highest product quality standards. We do not anticipate supply issues for Synvisc-One ® (hylan G-F 20) as a result of this voluntary product recall.

Your assistance with this voluntary product recall is greatly appreciated.

Thank you.

Sincerely,



Isabel Simons
Genzyme Recall Leader
Sanofi Genzyme
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