

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

The purpose of this notice is to inform you that B. Braun Medical Inc. (BBMI) is issuing a pharmaceutical recall for product L8001, 0.9% NACL INJ USP 500ML, due to potential fluid leakage.

BBMI has identified through complaints the potential for fluid leakage originating from pinholes in the same location of the bag. The size of the pinhole is small and therefore leakage only occurs when physical pressure is applied to the bag.

To date there have been no reports of serious injury or death associated with this issue. Product leakage can result in solution on the floor/surfaces requiring cleanup, a potential for falls/slips and/or the potential delay of treatment while a new IV bag is obtained. If the bag contains hazardous medication, there is a potential for leakage of that medication with limited to significant exposure to hazardous drugs, that may result in mild to severe injury to the patient, clinician, or others. If the leakage is not evident, the contents of the container may be contaminated due to compromising the sterile barrier of the product, potentially resulting in bloodstream infection. In some patients, such as immunocompromised patients and neonates, a bloodstream infection is a life-threatening event.

Product Catalog Number	NDC Number	Product Description	Lot Number	Distribution Range	Expiration Date	Region Distributed
L8001	0264-7800-10	0.9% NACL INJ USP 500 ML	J4L260	10/7/24-11/14/24	2/28/27	US
L8001	0264-7800-10	0.9% NACL INJ USP 500 ML	J4L261	10/7/24-11/12/24	2/28/27	US
L8001	0264-7800-10	0.9% NACL INJ USP 500 ML	J4L270	10/8/24-11/14/24	2/28/27	US
L8001	0264-7800-10	0.9% NACL INJ USP 500 ML	J4L271	10/10/24-11/14/24	2/28/27	US

L8001	0264- 7800-10	0.9% NACL INJ USP 500 ML	J4L280	10/9/24- 12/19/24	2/28/27	US