
From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, November 09, 2017 2:34 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Recall notice - Owen Mumford

Owen Mumford has identified a potential sterility issue and is issuing a voluntary recall for Lot #1705722 of Unifine Pentips 5mm pen needles. This lot was packed into two products, including Unifine Pentips 5mm 100ct pen needles (2,660 boxes: AN 3550 Batch# 1705722.8846), and Unifine Pentips 5mm 30ct pen needles (708 boxes: AN 1150 Batch #1705722.T098). This recall notice applies only to Lot 1705722, and is made to the End User level.

A device was identified to have been potentially compromised by water, in end user level packaging. Exposure to liquid may compromise sterility. This may appear as discoloring or yellowing of the device's protective seal. The product was discovered on-site, within Owen Mumford's control. The remaining lot has been placed on hold. Following third party laboratory evaluation, Owen Mumford has confirmed this affected product has come in contact with water {H2O}.

The batch number may be found on the label on the bottom of the box or, in the event that the box cannot be located, the lot number can be found on the device's protective seal.

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.

Product:	Owen Mumford Unfine Pentips 5mm	
Product Code:	AN 3550	AN 1150
NDC#:	08470-3550-01	08470-1150-01
UPC#:	3-8470355001-8	3-8470115001-2
Lot No.:	1705722	1705722
Batch.:	1705722.8846	1705722.T098
First Distributed:	August 23, 2017	October 04, 2017