

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.

Convatec is conducting a field action (removal) of specific lots of ESENTA Stomahesive Paste due to a quality related issue involving the potential presence of foreign matter within the product.

Through routine complaint handling and quality monitoring activities, a product quality issue was identified involving the presence of foreign matter in certain units of ESENTA Stomahesive Paste.

Subsequent investigation determined that existing controls at a third-party manufacturing facility were not fully effective in preventing contamination of Convatec materials. As a result, there is the potential for foreign contamination of affected product lots listed within the scope of this notification.

Based on the investigation findings and as a precautionary measure to protect product quality and patient safety, Convatec is voluntarily recalling the affected lots of ESENTA Stomahesive Paste.

The presence of foreign matter in the affected product may impact product quality and intended performance. Potential adverse effects associated with the use of affected product may include local inflammatory response, minor infection, skin irritation, rash, mucosal irritation, or allergic reaction.

The quality defect may be detected through visual inspection prior to application or use. To date, no adverse events related to this issue have been reported to Convatec. One (1) customer complaint involving foreign matter was received and led to the investigation and subsequent corrective action.

Product Code	Affected LOTs	Product Description	Primary UDI
1729233	6C03499	ESENTA SHESIVE PASTE (1X60G TUBE)	00768455169900
1729236	5K03776	ESENTA SHESIVE PASTE (1X56.7G TUBE)	00768455169931
	5L00431		
	5L00432		
	5L02607		
	5M02351		
	5M03521		
	6A04022		
	6E01525		
	6E05356		

	6E05929		
1739996	5J04201 5K00858 5L00433 5L02930 6A03082 6B00827 6E01386 6E03598	ESENTA S/HESIVE PASTE 1TUBEX56.7G	00768455209255
1739997	6C03991	ESENTA S/HESIVE PASTE 1TUBEX60G	00768455209262
1739998	6B00828 6C05168 6D02979	ESENTA S/HESIVE PASTE 1TUBEX60G	00768455209279
1739999	6A03083 6B00830 6D00838 6E01524	ESENTA S/HESIVE PASTE 1TUBEX60G	00768455209286
1740000	6A04010	ESENTA S/HESIVE PASTE 1TUBEX60G	00768455209293
1740002	6C03980 6D00839 6E03597	ESENTA S/HESIVE PASTE 1TUBEX60G	00768455209316
1740003	6E01523	ESENTA S/HESIVE PASTE 1TUBEX60G	00768455209323