

PROVIDER ALERT

Legacy Pharmaceutical Packaging, LLC – Losartan Potassium Tablets Drug Recall Notification

To: From:	Alliance Contracted Pharmacies Alliance Pharmacy Services Department	Recall Class: Recall Issue Date:	<i>Not yet classified</i> 03/15/2019	
Date:	04/29/2019	Recall #:	Not yet classified	
Subject:	DRUG RECALL NOTICE	Manufacturer:	Legacy Pharmaceutical	
			Packaging, LLC	
Products:	Medi-Cal, Group Care	Reason:	Impurity or contaminant detection	

DRUG AFFECTED	NDC	LOT #	EXPIRATION DATE
Losartan Potassium Tablets, USP 50 mg – 30-count	68645-494-54	180190	10/2020
Losartan Potassium Tablets, USP 50 mg – 30-count	68645-494-54	180191	10/2020
Losartan Potassium Tablets, USP 50 mg – 30-count	68645-494-54	181597	02/2021

Source: www.fda.gov/Safety/Recalls/ucm633671.htm



Image above reflects an example of recalled drug.

Questions? Please call the Alliance Pharmacy Services Department Monday – Friday, 8 am – 5 pm Phone Number: **1.510.747.4541** www.alamedaalliance.org Legacy Pharmaceutical Packaging, LLC has issued a recall of **three (3)** repackaged lots of **Losartan Tablets, USP 50 mg** to the consumer level. This recall was prompted due to Torrent Pharmaceuticals, Ltd. recent voluntary nationwide recall of Losartan Tablets, USP due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs, Ltd. Legacy Pharmaceutical Packaging, LLC has advised that NMBA is a potential human carcinogen. To date, Legacy has not received any reports of adverse events related to this recall.

Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Any general questions regarding the return of this product should be directed to:

Inmar Pharmaceutical Services Monday – Friday, 9 am – 5 pm (EST) Toll-Free: **1.877.538.8443**

<u>Consumers, pharmacies, and healthcare facilities that have the recalled product should stop using and dispensing immediately.</u>

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Online: Complete and submit the report at www.fda.gov/medwatch/report.htm
- Regular Mail or Fax:
 - Download the form at www.fda.gov/MedWatch/getforms.htm
 - o To request a reporting form, please call toll-free at 1.800.332.1088
 - Please complete and return to the address on the pre-addressed form, or submit by fax to **1.800.FDA.0178 (1.800.332.0178)**