

Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Legacy Pharmaceutical Packaging, LLC Expands Voluntary Nationwide Recall of Losartan Potassium Tablets, USP, 50mg Due to the Detection of Trace Amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) Impurity Found in the Active Pharmaceutical Ingredient (API)

For Immediate Release

April 24, 2019

Contact

Consumers

☎ 1-877-538-8443

Announcement

[View Product Photos](#)

Legacy Pharmaceutical Packaging, LLC is expanding its consumer-level recall of 3 repackaged lots Losartan Tablets USP 50mg to include one additional lot. This recall was prompted due to Torrent Pharmaceuticals LTD issuing a 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 Limited, (API manufacturer).

NMBA is a potential human carcinogen. To date, Legacy has not received any reports of adverse events related to this recall.

Losartan Potassium USP is a prescription medication used to treat high blood pressure and congestive heart failure and is packaged in 30ct bottles. The identifying NDC number associated with Legacy's product is as follows:

Losartan Potassium, USP, 50mg NDC 68645-494-54

The affected Losartan Potassium includes 4 repackaged lots numbers (3 initial repackaged lot and 1 expanded repackaged lot) which are listed below:

LEGACY NDC#	Name and Strength	Count	Legacy Lot #	Expiry
68645-494-54	Losartan Potassium Tablets USP 50 mg	30	180190	10/2020
68645-494-54	Losartan Potassium Tablets USP 50 mg	30	180191	10/2020
68645-494-54	Losartan Potassium Tablets USP 50 mg	30	181597	02/2021
68645-494-54	Losartan Potassium Tablets USP 50 mg	30	181598	02/2021

The product can be identified by checking the product name and repackaged lot number on the bottle containing these products.

Losartan Potassium was distributed by pharmacies nationwide. Legacy Pharmaceutical Packaging LLC is notifying its distributors and customers in writing and is arranging/assisting for return of all recalled products to Inmar Pharmaceutical Services. Instructions for returning recalled products are provided in the recall letter.

Consumers with questions regarding this recall can contact Inmar at 1-877-538-8443, Monday – Friday, 9am – 5pm EST. Consumers should contact their physician or healthcare provider if they have that may be related to taking or using this drug product.

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

- **Complete and submit the report Online:**
<http://www.fda.gov/medwatch/report.htm> www.fda.gov/medwatch/report.htm
<http://www.fda.gov/medwatch/report.htm>
- **Regular Mail or Fax: Download form** (<http://www.fda.gov/MedWatch/getforms.htm>) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

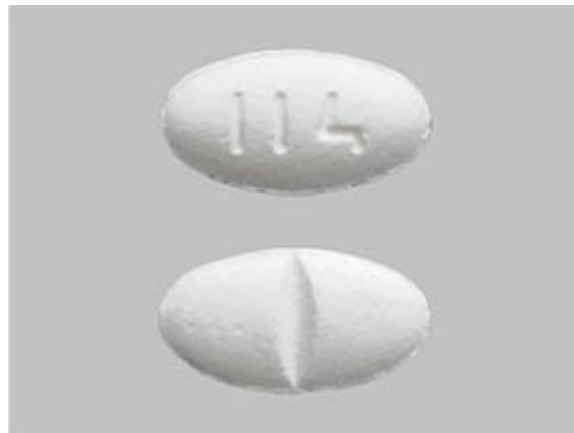
[Initial Press Release \(/Safety/Recalls/ucm633664.htm\)](http://www.fda.gov/Safety/Recalls/ucm633664.htm)

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