



Torrent – Recall of losartan-containing products

- On September 19, 2019, the [FDA announced](#) a consumer-level recall of several lots of Torrent's [losartan](#) and [losartan/hydrochlorothiazide \(HCTZ\)](#) tablets due to the detection of trace amounts of N-Methylnitrosobutyric acid (NMBA) in the active pharmaceutical ingredient (API) manufactured by Hetero Labs.
 - This recall is the fifth expansion to the original Torrent recall announced on January 3, 2019.
- Refer to the [FDA site](#) for updates regarding angiotensin II receptor blocker recalls.

Product Description	NDC#	Lot# (Expiration Date)
Losartan 50 mg	13668-409-10	4DU2E009 (12/31/2020)
Losartan 100 mg	13668-115-90	4DU3E009 (12/31/2020)
	13668-115-10	4DU3D018 (2/28/2021)
Losartan/HCTZ 50 mg/12.5 mg	13668-116-90	BEF7D051 (11/30/2020)
Losartan/HCTZ 100 mg/25 mg	13668-118-90	4P04D007 (7/31/2020)

- Losartan and losartan/HCTZ tablets are used for the treatment of hypertension (HTN) and to reduce the risk of stroke in patients with HTN and left ventricular hypertrophy. Losartan tablets are also used for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio ≥ 300 mg/g) in patients with type 2 diabetes and a history of HTN.
- Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on a losartan-containing product should continue taking their medication, as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled losartan-containing product.
- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.
- Any general questions regarding the return of the recalled product should be directed to Qualanex at **1-888-280-2040**. For medical questions or to report an adverse event contact Torrent at **1-800-912-9561**.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2019 Optum, Inc. All rights reserved.