

**SAFETY RECALL**  
**CHILD RESISTANT PACKAGING**  
**Ezetimibe 10mg Tablets (30 and 90 count bottles)**  
**and Losartan Potassium 50mg Tablets (30 count bottles)**

August 2019

Dear Patient:

Sandoz Inc. ("Sandoz"), in cooperation with the U.S. Consumer Product Safety Commission ("CPSC") and U.S. Food and Drug Administration ("FDA"), is voluntarily implementing a CPSC-approved corrective action plan for specific lots of 30 count and 90 count bottles of Ezetimibe 10mg Tablets and one 30 count bottle lot of Losartan Potassium 50mg Tablets distributed in the United States. **This action is not a result of any quality or safety concerns with the medications for their intended use.**

The cap and bottle combination used to package particular lots of Ezetimibe 10mg Tablets and Losartan Potassium 50mg Tablets, as outlined in the table below, is not child resistant, posing a risk of harm if the tablets are swallowed by children. As a result, Sandoz is offering a free replacement child resistant bottle cap to patients having these particular lots of medication. Please be aware that other lots of Ezetimibe 10mg Tablets distributed after April 2019 use a different cap, are child resistant, and comply with CPSC regulations.

**PATIENT ACTION:**

The quality of Ezetimibe 10mg Tablets and Losartan Potassium 50mg Tablets has not been compromised, so you should continue taking your medication as directed by your physician. However, due to the risk of harm to children, **immediately secure the medication out of the sight and reach of children.**

Sandoz will provide you with a free replacement child resistant bottle cap to secure your medication. Please order a free replacement child resistant bottle cap by calling Sandoz toll free at 800-525-8747 from 8:30am – 5:00pm EST Monday through Friday and provide the following information:

- Patient name, address and telephone number
- Number of Ezetimibe Tablet and/or Losartan Potassium Tablet bottles in your possession.

We will then ship you a free replacement child resistant bottle cap for your existing Sandoz bottle. Additional information regarding this voluntary recall is available at [www.us.sandoz.com/patients-customers/product-safety-notice](http://www.us.sandoz.com/patients-customers/product-safety-notice).

**This notification applies only to the following NDC and lot numbers:**

Product Description	NDC Number	Lot Number	Expiration Date
Ezetimibe 10mg Tablets 30 count bottle	0781-5690-31	JE4491	Aug-2020
		JE4492	Aug-2020
		JE4493	Aug-2020
		JE4495	Aug-2020
		JG0308	Sep-2020
		JG0310	Sep-2020
		JG0311	Sep-2020
		JG0312	Sep-2020
		JG5061	Sep-2020
		JG5063	Sep-2020
		JK8921	Oct-2020
		JK8922	Oct-2020
		JK8923	Oct-2020
		JK8924	Oct-2020
		JL5535	Oct-2020
		JM2253	Oct-2020
		JM2254	Oct-2020
		JM2255	Oct-2020
		JM2257	Oct-2020
		JM2258	Oct-2020
JM2259	Oct-2020		
JM5986	Oct-2020		
JM5987	Oct-2020		
Ezetimibe 10mg Tablets 90 count bottle	0781-5690-92	JE4481	Aug-2020
		JG0249	Sep-2020
		JK8989	Oct-2020
		JN0764	Jan-2021
Losartan Potassium 50mg Tablets 30 count bottle	0781-5701-31	HV9471	Feb-2020

**Other Information:**

Any medical related inquiries should be directed to Sandoz at 800-525-8747 or visit <https://www.us.sandoz.com/patients-customers/products>. Please report any adverse events by calling Sandoz at 800-525-8747 or emailing Sandoz at [qa.drugsafety@sandoz.com](mailto:qa.drugsafety@sandoz.com). Adverse events can also be reported to FDA online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm).

We appreciate your immediate attention and cooperation and apologize for this situation.

Sincerely,

Emma Harrington  
Head, Novartis Country Quality US