# Worldwide Valsartan Recall

**Please note that this fact sheet is not intended to be published in its current form, but rather used to provide evidence and resources for an original article. We would be happy to provide an original guest post on the subject matter for free. Please contact Caitlin Hoff at choff@consumersafety.org for more information.**

According to the World Health Organization (WHO), 1.13 billion people worldwide suffer from high blood pressure, also known as hypertension. This statistic became extremely important this summer when a popular generic medication used to treat hypertension was recalled in 23 countries due to a contaminated ingredient. Here is what you need to know about the latest developments in the worldwide Valsartan recall.

## Valsartan

Valsartan is a medication originally developed by the Swiss company Novartis and sold under brand names including Diovan, Entresto, and Exforge. It is used to treat hypertension, heart failure, and other related conditions. After Diovan's patent expired in 2012, valsartan has since been used by multiple companies to manufacture generic drug options for consumers.

## The Recall

- **July 5, 2018:** The European Medicines Agency (EMU) along with the health and safety governing bodies of 21 other countries recalled several batches of valsartan medications due to a potentially carcinogenic impurity found in the medication.
- **July 13, 2018:** The U.S. Food and Drug Administration (FDA) became the 23rd country to recall several valsartan products due to safety concerns.
- **July-August 2018:** The FDA continued to expand the recall as impurities were found in more medications containing valsartan.
- **September 13, 2018:** The FDA found a second possibly cancer-causing impurity in "three lots of Torrent Pharmaceuticals' recalled valsartan drug products."

## The Impurities

Initially, the first impurity found in the recalled products was N-nitrosodimethylamine (NDMA). NDMA is classified as a probable human carcinogen. According to the U.S. Environmental Protection Agency (EPA), increased exposure to NDMA may cause liver damage and has been shown to cause tumor growth in the liver, respiratory tract, kidney and blood vessels of animals during experimental studies. Further investigations have determined that the impurity was accidentally created through a chemical process during manufacturing.

The second impurity found in September is known as N-nitrosodiethylamine (NDEA). Like NDMA, evidence has linked cancer with NDEA in animal test subjects, making it a probable human carcinogen as well. The long-term cancer risks of NDEA and NDMA exposure for humans is currently unknown.

Companies whose medications were recalled sourced their valsartan API (active pharmaceutical ingredient) from three main pharmaceutical manufacturing companies:

- Zhejiang Huahai Pharmaceuticals
- Zhejiang Tianyu Pharmaceutical

- Hetero Labs Limited

## How Should Consumers Proceed?

It's important to recognize that not all drug products containing valsartan were included in the recall. Valsartan itself is not the reason for the recall; the contaminated impurities created in the manufacturing process are to blame. Therefore, medications like the brand-name products Diovan and Entresto were not included in the recall because their valsartan API was not supplied by one of three companies found to have a contamination problem in their manufacturing process.

Anyone taking a medication containing valsartan should review the name of the drug and company name to determine if their medication was recalled. If you cannot find this information, you can call the pharmacy that filled your prescription to get this information. The FDA has published and is frequently updating a list of recalled medications and a list of medications not affected by the recall.

All patients taking a recalled valsartan drug product should contact their doctor immediately to discuss switching to a non-affected valsartan product or an alternative blood pressure medication. **However, those patients should NOT stop taking their medication until a replacement has been obtained.**