Polypharmacy Network Newsletter

Welcome to the Polypharmacy Network's inaugural newsletter! Our newsletter is dedicated to highlighting a medication use topic and share Polypharmacy Network style analysis and perspective.

The information provided in our newsletter is not meant to replace your healthcare provider's expertise and management (doctor, NP, Pharmacist, or other provider); but our purpose is to help your self-monitoring of medication use, make informed choices and have informed conversations with your healthcare providers about your medication use.

Drugs containing valsartan were pulled from market in 22 countries due to potential contamination with potential carcinogen NDMA.

This recall was issued by the manufacturers of several drugs involving five companies. The brand name for valsartan is "Diovan", was not affected, but there are several generic brands on the market and some combination products containing valsartan.

The recall involves about 2,300 batches that were sent to Germany, Norway, Finland, Sweden, Hungary, the Netherlands, Austria, Ireland, Bulgaria, Italy, Spain, Portugal, Belgium, France, Poland, Croatia, Lithuania, Greece, Canada, Bosnia and Herzegovina, Bahrain and Malta. Currently the FDA is monitoring the situation, although the **United States has not to date been affected.**

Valsartan supplied by Zhejiang Huahai Pharmaceuticals of China contain an impurity called N-nitrosodimethylamine (NDMA). NDMA is a potential potent carcinogen that could cause cancer with long-term exposure. NDMA is used to make liquid rocket fuel, softeners and lubricants among other products. It can be unintentionally produced via various chemical reactions and can be a byproduct of some pesticide manufacturing, rubber tire production and fish processing.

Zhejiang Huahai Pharmaceuticals notified the European Medicines Agency (EMA), the FDA and other stake holders that they detected an impurity, NDMA, in the active substances which the company supplies to manufacturers producing some of the valsartan medicines.

It is important NOT to suddenly stop taking these medications because they treat serious conditions such as high blood pressure, and heart failure. If you have concerns because you live in an affected area, please consult your doctor or pharmacist.

Contaminated blood pressure drug, valsartan, recalled.

A recall was issued by the manufacturers of several drugs containing the generic drug called valsartan, when the producer of the active drug ingredient discovered an impurity called NDMA, a potentially potent carcinogen (cancer causing agent). The recall involved five companies.

The brand name for valsartan is "Diovan®", was not affected, and the brand name combination drug called "Entresto®" was not affected. There are several generic brands on the market and some combination products containing valsartan.

Products containing valsartan include; generic (brand name):

Valsartan; (Diovan®)

Valsartan and Hydrochlorothiazide; valsartan-HCTZ; (Diovan HCT®)

Valsartan and Amlodipine (Exforge®)

Valsartan, Amlodipine and Hydrochlorothiazide (Exforge HCT®)

Valsartan and Sacubitril (Entresto®)

What does this mean regarding other products?

One of the important concepts to understand is that products are sources from various factories all around the world. Note that the brand name products in this case were not affected in this case. This was primarily coincidence in this case, however if you consider that generic manufacturing is a larger scale worldwide enterprise, it is less likely that quality controls would be as strict just by increased random chance than for the brand name product. Whether a consumer has access to brand name product or closely controlled quality is a complex discussion for another time.

The point is that **the manufacturing process can introduce an element of risk** in medication (and product use) that most people don't consider until something goes wrong. Regarding prescription and over the counter medications, there's not much consumers can do to avoid the type of error such as the recent valsartan problem detected outside the United States.

But, dietary supplements are not regulated by the FDA in the same way that prescription and over the counter medications are (those with NDC or national drug code numbers).

The USP (United States Pharmacopeia) has a program called USP verified. USP verified dietary supplements (USP emblem on bottle) means the manufacturer voluntarily agrees for quality assurance spot checks to ensure product inside container is what is listed on the label. The USP verified symbol is depicted in Figure 1 and can be found on the label of participating products.

Figure 1: United States Pharmacopeia (USP) "Verified" symbol

Numerous dietary supplements are pulled off the market by the FDA monthly because of "contaminated" ingredients. Sometimes the contamination is due to actual prescription medication ingredients in the product instead of the herbal product listed on the label. This is a common problem with sexual enhancement (erectile dysfunction) products. To find out more, go to the Polypharmacy Network website and click on Polypharmacy Knowledge and Herbals and Supplements or
click here => http://polypharmacynetwork.org.

Take Home Message

Prescription Medications, Over the Counter Medications (OTC), and Dietary Supplements can contain tainted ingredients. Be aware of this risk. Prescription and OTC medications are closely regulated by the FDA, but the increased number of products on the market and worldwide sourcing of ingredients increases the risk of contamination.

Try to source quality dietary supplements if possible because dietary supplements are not subject to the same FDA product manufacturing standards as prescription and OTC medications.