

Laboratory analysis of valsartan products

FDA continues to investigate the presence of impurities in valsartan products and other angiotensin II receptor blockers (ARBs) used to treat high blood pressure and heart failure. FDA recently identified the impurities N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) in certain valsartan products. FDA is posting its test results showing NDMA levels in recalled valsartan products. FDA will also post test results and an assessment of the cancer risk from NDEA when they are available.

The table below shows the NDMA test results for the recalled valsartan products. The analyses reflect average levels of NDMA present in a single tablet based on the strength of the tested drug product within the lots tested, which are identified in the table. Some of products listed below may have been repackaged by other companies as noted in FDA's [list of valsartan products under recall \(https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615703.pdf\)](https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615703.pdf). For reference, consuming up to 0.096 micrograms of NDMA per day is considered reasonably safe for human ingestion based on lifetime exposure.

FDA previously estimated that if 8,000 people took the highest valsartan dose (320 mg) containing NDMA from the recalled batches daily for four years, there may be one additional case of cancer over the lifetimes of the 8,000 people. That estimate was based on the highest daily dose, however many people may have taken lower doses, and therefore their risks would theoretically be less. FDA expects the actual cancer risk to most consumers to be lower than our estimate.

Company	Product (tablets)	Lots Tested	NDMA level (micrograms - mcg/tablet)
Hetero Labs Ltd	Valsartan 320mg	VLS18049, VLS18051, VLS18050	0.3-0.4
Prinston Pharmaceutical	Valsartan 320mg/HCTZ 25mg	611B18025, 611B18026, 611B18027	13-20
Prinston Pharmaceutical	Valsartan 320mg	344B18027, 344B18028, 344B18029	15-16
Teva Pharmaceuticals	Valsartan 320mg	1240425A, 1247282M, 1263943A	8-17
Teva Pharmaceuticals	Valsartan 320mg/HCTZ 25mg	1217576M, 1217577M, 1217578M	7-10
Torrent Pharmaceuticals	Amlodipine 10mg/Valsartan 320 mg/HCTZ 25mg	BBX2E001, BBX2E002, BBX2E003	10-12
Torrent Pharmaceuticals	Amlodipine 10mg/Valsartan 320 mg	BV77E001, BV77E002, BV77E003	5-9

Torrent Pharmaceuticals	Valsartan 320mg	BV48D001, BV48D002	0.5-0.6
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