

[Blood Pressure Medication Benicar \(Olmesartan\) Might Be Unsafe For Some Patients](#)

Two Clinical Studies Find Patients With Type 2 Diabetes Taking Benicar Had Higher Rate Of Death From A Cardiovascular Cause

(Posted by Tom Lamb at www.DrugInjuryWatch.com on June 11, 2010; see <http://bit.ly/9WfG8G>)

On June 11, 2010 the FDA announced that it had issued a safety alert about the blood pressure medication Benicar (olmesartan) which was titled "[FDA Drug Safety Communication: Ongoing safety review of Benicar and cardiovascular events](#)". Benicar is also sold in combination with hydrochlorothiazide as Benicar HCT for the treatment of high blood pressure. Benicar is in the class of drugs called angiotensin II receptor blockers (ARBs).

From this June 2010 FDA announcement:

The U.S. Food and Drug Administration (FDA) is evaluating data from two clinical trials in which patients with type 2 diabetes taking the blood pressure medication, Benicar (olmesartan) had a higher rate of death from a cardiovascular cause compared to patients taking a placebo. Benicar (olmesartan) is also sold in combination with hydrochlorothiazide as Benicar HCT for the treatment of high blood pressure.

FDA's review is ongoing and the Agency has not concluded that Benicar increases the risk of death. FDA currently believes that the benefits of Benicar in patients with high blood pressure continue to outweigh its potential risks.

The Agency plans to review the primary data from the two studies of concern, ROADMAP and ORIENT, and is considering additional ways to assess the cardiovascular effects of Benicar.

We get some additional information and explanation from a June 11, 2010 article, "[Cardiovascular Events Trigger FDA Review of ARB](#)", by Peggy Peck of *MedPage Today*:

There were 15 cardiovascular deaths in the olmesartan arm of the 4,447-patient Randomized Olmesartan and Diabetes Microalbuminuria Prevention Study (ROADMAP) trial versus three in the placebo arm, and in the much smaller Olmesartan Reducing Incidence of End Stage Renal Disease in Diabetic Nephropathy Trial (ORIENT) study (with 566 patients), there were 10 cardiac deaths among patients taking olmesartan versus three in the placebo group....

The FDA said it planned to review the primary data from the two trials and the total clinical trial data on olmesartan to evaluate the possible association between olmesartan and increased cardiovascular-related death....

Both clinical trials were designed to determine if treatment with olmesartan, which is an angiotensin II receptor blocker (ARB), could slow the progression of kidney disease.

The FDA noted that clinical trials of other ARBs as well as other trials of olmesartan have not revealed an excess risk of cardiovascular mortality.

Benicar and Benicar HCT are marketed by Daiichi Sankyo, Inc., which has a U.S. headquarters in Parsippany, N.J.

We will continue to monitor the safety profile of Benicar and report any significant developments here at the Drug Injury Watch blog.

Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.

<http://www.DrugInjuryWatch.com>