

SPINE SAFETY WARNING:

Information for Healthcare Professionals: Benicar (olmesartan medoxomil) Tablets: Labeling Changes

According to MedWatch, FDA notified healthcare professionals of labeling changes for Benicar (olmesartan medoxomil) Tablets. The following has been added to the labeling:

June 2011

DRUG INTERACTIONS

Non-Steroidal Anti-Inflammatory Agents including Selective Cyclooxygenase-2 Inhibitor(COX-2 Inhibitors)

- In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, co-administration of NSAIDs, including selective COX-2 inhibitors with angiotensin II receptor antagonists, including olmesartan medoxomil, may result in deterioration of renal function, including possible acute renal failure. These effects are usually reversible. Monitor renal function periodically in patients receiving olmesartan medoxomil and NSAID therapy.
- The antihypertensive effect of angiotensin II receptor antagonists, including olmesartan medoxomil may be attenuated by NSAIDs including selective COX-2 inhibitors.

May 2011

ADVERSE REACTIONS

Postmarketing Experience

- Anaphylactic reactions

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members.

Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.