

SPINE SAFETY WARNING:

Information for Healthcare Professionals:

Tribenzor (olmesartan medoxomil / amlodipine / hydrochlorothiazide) tablets: Labeling Changes

According to MedWatch, FDA notified healthcare professionals of labeling changes for Tribenzor (olmesartan medoxomil / amlodipine / hydrochlorothiazide) tablets. The following has been added to the labeling:

June 2011

DRUG INTERACTIONS

Olmesartan medoxomil

- Nonsteroidal anti-inflammatory drugs (NSAIDs): May lead to increased risk of renal impairment and loss of antihypertensive effect

CLINICAL TRIALS

- There are no trials of Tribenzor demonstrating reductions in cardiovascular risk in patients with hypertension, but at least one pharmacologically similar drug has demonstrated such benefits.

March 2011

WARNINGS AND PRECAUTIONS

Acute Myopia and Secondary Angle-Closure Glaucoma

- Hydrochlorothiazide, a sulfonamide, can cause an idiosyncratic reaction, resulting in acute transient myopia and acute angle-closure glaucoma. Symptoms include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of drug initiation. Untreated acute angle-closure glaucoma can lead to permanent vision loss. The primary treatment is to discontinue hydrochlorothiazide as rapidly as possible. Prompt medical or surgical treatments may need to be considered if the intraocular pressure remains uncontrolled. Risk factors for developing acute angle-closure glaucoma may include a history of sulfonamide or penicillin allergy.

ADVERSE REACTIONS

Post-Marketing Experience

- anaphylactic reactions, peripheral edema, diarrhea

DRUG INTERACTIONS

Drug Interactions with Olmesartan Medoxomil

- Non-Steroidal Anti-Inflammatory Agents including Selective Cyclooxygenase-2 Inhibitors (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, 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 and NSAID therapy.
- The antihypertensive effect of angiotensin II receptor antagonists, including olmesartan may be attenuated by NSAIDs including selective COX-2 inhibitors.

PATIENT LABELING

What are the possible side effects of Tribenzor?

- Eye problems. One of the medicines in Tribenzor can cause eye problems that may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of starting Tribenzor. Tell your doctor right away if you have:
 - decrease in vision
 - eye pain

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.