

SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals: Avalide (irbesartan/hydrochlorothiazide) tablets: Labeling Changes

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

WARNINGS

Acute Myopia and Secondary Angle-Closure Glaucoma

- Sulfonamide or sulfonamide derivative drugs, such as hydrochlorothiazide, can cause an idiosyncratic reaction, resulting in transient myopia and acute angle closure glaucoma. Cases of acute angle-closure glaucoma have been reported with hydrochlorothiazide. 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 drug intake 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.

DRUG INTERACTIONS

Irbesartan

- No significant drug-drug interactions have been found in interaction studies with hydrochlorothiazide, digoxin, warfarin, and nifedipine.
- *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 irbesartan, may result in deterioration of renal function, including possible acute renal failure. These effects are usually reversible. Monitor renal function periodically in patients receiving irbesartan and NSAID therapy.
- The antihypertensive effect of angiotensin II receptor antagonists, including irbesartan may be attenuated by NSAIDs including selective COX-2 inhibitors

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.