

SPINE SAFETY WARNING:

Information for Healthcare Professionals:

Tekturna (aliskiren) and Tekturna HCT (aliskiren/hydrochlorothiazide) Tablets: Labeling Changes

According to MedWatch, FDA notified healthcare professionals of labeling changes for Tekturna (aliskiren) and Tekturna HCT (aliskiren/hydrochlorothiazide) Tablets. The following has been added to the labeling:

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.

Cyclosporine or Itraconazole

- Aliskiren: When aliskiren was given with cyclosporine or itraconazole, the blood concentrations of aliskiren were significantly increased. Avoid concomitant use of aliskiren with cyclosporine or itraconazole

ADVERSE REACTIONS

Post-Marketing Experience

- Blood creatinine increased

DRUG INTERACTIONS

Aliskiren

- Cyclosporine: Avoid co-administration of cyclosporine with aliskiren.
- Itraconazole: Avoid co-administration of itraconazole with aliskiren.

Patient Labeling

What are the possible side effects of Tekturna HCT?

- Eye problems. One of the medicines in Tekturna HCT can cause eye problems that may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of starting Tekturna HCT. 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.