FDA Approves Changes to Reyataz Label

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The U.S. Food and Drug Administration (FDA) has approved changes to the label of the antiretroviral Reyataz (atazanavir) to include new warnings about kidney and gall stones, a kidney dysfunction known as interstitial nephritis, as well as updated drug interaction information.

In a release, the FDA states that there have been anecdotal reports of kidney and gall stones (nephrolithiasis and cholelithiasis) among people taking Reyataz, which in some cases have required hospitalization. The FDA advises that if you experience signs or symptoms of kidney or gall stones, then you should consider a temporary interruption or discontinuation of the medication.

The FDA added interstitial nephritis, in which the spaces between the kidney tubules become inflamed, to the adverse reactions section of the Reyataz label.

The additional drug interactions include:

Boosted Reyataz (atazanavir/ritonavir) is not recommended with the hepatitis C antiviral Victrelis (boceprevir), as Victrelis can reduce levels of Reyataz.

The anticonvulsant Tegretol (carbamazepine) can reduce levels of Reyataz when it is taken without ritonavir; therefore, taking Tegretol and Reyataz without ritonavir is not recommended.

The antiepileptic Dilantin (phenytoin) or the barbiturate/anticonvulsant phenobarbital are not recommended in combination with Reyataz unless ritonavir is used as a booster to counteract a lowering of Reyataz levels.

Reyataz and ritonavir taken together with the antiseizure drug Lamictal (lamotrigine) may decrease Lamictal levels, requiring a dose adjustment of Lamictal. Reyataz taken without ritonavir should not have this effect on Lamictal levels.

The antifungal medication Vfend (voriconazole) should not be taken with Reyataz/ritonavir without assessing the risks versus benefits, specifically the Vfend-related adverse effects and the loss of either Vfend or Reyataz's efficacy. Voriconazole may affect Reyataz levels, but there is no available data to support this.

To read the FDA release, click here.

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http://beta.docker.poz.com/article/reyataz-label-23469-3439