Workers' Comp

AvKARE Issues Voluntary Nationwide Recall of Certain Sildenafil and Trazodone Tablets

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2 MIN READ

AvKARE, Inc., a subsidiary of Amneal Pharmaceuticals located in Pulaski, Tennessee, announced a voluntary recall today, to the consumer level, for several lots of sildenafil and trazodone tablets (see table below) because they were “inadvertently packaged together” by a third-party vendor.

Sildenafil, a treatment for erectile dysfunction, is the active ingredient in Viagra and trazodone is an antidepressant medication with sedating properties that is also prescribed off-label to promote sleep.

Unintended consumption of sildenafil may pose serious health risks, including dangerous blood pressure lowering, for persons who are also prescribed and taking nitrate medications (like nitroglycerin tablets) for the management of angina (chest pain) symptoms. Persons with diabetes, hypertension or heart disease may also be more likely consumers of nitrate medications.

Unintended consumption of trazodone may result in somnolence/sedation, dizziness, constipation or blurred vision. These adverse events may be of special concern in elderly patients related to an increased risk for falls and related injuries, as well as driving impairment.

The product mix-up, announced Wednesday by AvKARE, has not yet prompted any reports received by them, of adverse events related to this recall. They have notified distributors and customers to arrange for the return of all affected product. Persons prescribed either sildenafil or trazodone should contact their physician, pharmacy or healthcare provider with questions about continued use.

The Impact

Sildenafil and trazodone tablets are a small fraction of all prescribed medications across the First Script book of business. We are currently reviewing prescriptions within our system that may have been dispensed with the affected sildenafil or trazodone products and will contact those impacted, should we identify either product.

If you have any questions about this alert, please contact your client services manager.



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